

Protocol No. 212853

Final Report

Investigation title	Shingrix for Intramuscular Injection Drug Use Investigation
Protocol No.	212853
Date of final report preparation	April 28, 2026
Proprietary name	Shingrix for Intramuscular Injection
Active ingredient	Varicella-zoster virus gE antigen 50 µg
Marketing authorization holder (MAH: Marketing Authorization Holder)	GlaxoSmithKline K.K.

1. Synopsis of Protocol

Investigation title: Shingrix for Intramuscular Injection Drug Use Investigation	
Objective	To assess the presence or absence of issues and concerns regarding safety of Shingrix for Intramuscular Injection (hereinafter referred to as “Shingrix”) under practical use conditions.
AEs or ADRs of special interest	• Shock and anaphylaxis • Potential Immune-Mediated Disease (pIMD)
Effectiveness considerations	Not applicable
Investigation method	Central registration method: Subjects are registered by entering information required for registration into the EDC system by Day 8 after the first vaccination with Shingrix (the day of vaccination is designated as Day 1).
Target population	The target population of this investigation is individuals to receive Shingrix for the first time to prevent herpes zoster, for which Shingrix is indicated.
Investigation period	August 2020 to March 2025
Target sample size	15,000 doses (at least 7,500 subjects)
Observation period	The observation period for each subject is up to Day 30 following each vaccination (Day 1 - Day 30; the day of vaccination is designated as Day 1).
Observation items	Information on the medical institute Subject information Subject characteristics Vaccination status and related data Vaccines administered other than Shingrix Medications during observation period Non-drug therapies during observation period Pregnancy / Breast-feeding Adverse Event
Effectiveness evaluation criteria	Not applicable
Remarks	Protocol amendments: February 27, 2019: initial version created October 9, 2019: revision associated with succession January 24, 2020: (1) the investigation period changed, (2) the consent acquisition field organized, (3) the consent withdrawal field deleted, and (4) analysis items organized May 19, 2023: (1) the registration period and investigation period changed, (2) the organization structure for activities such as post-marketing surveillance added, (3) the reason for vaccination field added to the subject characteristics section in the case report form, and (4) the description of health observation diary organized January 16, 2024: the registration period and investigation period changed

2. Investigation Results

2.1. Number of Participating Sites and Subject Disposition

The drug use investigation (hereinafter referred to as “this investigation”) of Shingrix for Intramuscular Injection (hereinafter referred to as “Shingrix”) was started in August 2020 using a central registration method with the planned sample size of 15,000 doses (at least 7,500 subjects) in individuals to receive Shingrix for the first time to “prevent herpes zoster,” for which Shingrix is indicated (observation period: for 30 days after each vaccination). The subject disposition of this investigation is as shown in Figure 1 of Attachment 1 (“Attachment 1” is omitted in the subsequent figures and tables). A total of 7,830 subjects were registered in this investigation. Case report forms (CRFs) were collected from 7,712 subjects and then locked, excluding: 116 subjects from whom CRFs could not be collected and 2 subjects who withdrew consent. Five subjects with “registration deviations”¹ were excluded from those whose CRF data were locked, and 7,707 subjects were included in the safety analysis set. The numbers of subjects of the first and second vaccinations were 7,707 and 7,464, respectively, and cumulative total number of doses was 15,171. Adverse drug reactions (ADRs) were reported in 3 of 5 subjects who were excluded from the safety analysis set. Reported ADRs were “vaccination site erythema” and “vaccination site swelling” (3 each); “vaccination site pain,” “myalgia,” and “pyrexia” (2 each); and “chills” and “headache” (1 each). All ADRs were non-serious and their outcomes were “resolved.”

2.2. Subject Characteristics (Distribution)

Table 1-1 shows the characteristics of the 7,707 subjects in the safety analysis set. By sex, “female” was more common, accounting for 67.6% (5,212/7,707). The mean age $\pm$ SD (min-max) was 66.0 $\pm$ 10.3 (19-102) years; 1.2% (91/7,707) aged “ ≥ 15 to < 50 years,” 44.2% (3,406/7,707) aged “ ≥ 50 to < 65 years,” 32.7% (2,524/7,707) aged “ ≥ 65 to < 75 years,” and 21.9% (1,686/7,707) aged “ ≥ 75 years.” A history of herpes zoster was reported in 9.6% (742/7,707) of the subjects, and 0.5% (39/7,707) of the subjects were considered to require precaution for vaccination by the investigator. Immune abnormalities² were reported in 9.1% (702/7,707) of the subjects; the percentages of those reporting a history of underlying disease associated with immune abnormalities, prior medications (that may affect the immune system), and prior therapies (that may affect the immune system) were 8.7% (672/7,707), 8.2% (635/7,707), and 0.1% (8/7,707), respectively (multiple responses allowed). The most commonly reported underlying disease associated with immune abnormalities was “rheumatoid arthritis” (6.1%, 468/7,707), followed by “Sjogren’s syndrome” (0.4%, 33/7,707) (Table 1-2). The most commonly reported prior medication (that may affect the immune system) was methotrexate (3.7%, 287/7,707), followed by prednisolone (2.3%, 178/7,707) (Table 1-3). None of the subjects used immune checkpoint inhibitors as prior medications. Reported prior therapies (that may affect the immune system) were “dialysis” (0.1%, 5/7,707), “Radiotherapy” (0.0%, 1/7,707), “” and “surgery/other” (0.0%, 2/7,707) (allogeneic hematopoietic stem cell

¹ Doses excluded from safety analysis: “Registration deviations” 10 doses (5 doses in the first vaccinations and 5 doses in the second vaccination).

² Subjects with abnormal immune status due to underlying diseases associated with immune abnormalities, prior medications, or prior therapies

transplantation and breast cancer surgery, one subject each), as shown in Table 1-4. Underlying diseases were reported in 51.2% (3,946/7,707) of the subjects; underlying kidney diseases and underlying liver diseases were reported in 1.4% (110/7,707) and 2.2% (166/7,707), respectively. The numbers of subjects with underlying diseases by condition are as shown in Table 1-5.

2.3. Vaccination Status and Related Data

Table 2-1 shows the vaccination status and related data of the 7,707 subjects in the safety analysis set. Among the 7,707 subjects who received the first dose of Shingrix, 96.8% (7,464/7,707) received the second dose and 3.2% (243/7,707) did not. The main reasons the second dose was not received were “reasons of the vaccinee” (1.2%, 89/7,707), “no visits after the midpoint” (0.8%, 62/7,707), and “no visits after the day of the first vaccination” (0.5%, 37/7,707). The most commonly reported interval (days) between the first and second vaccinations with Shingrix was “ ≥ 55 to < 83 ” (64.7%, 4,989/7,707), followed by “ ≥ 83 to < 111 ” (17.4%, 1,342/7,707). The most commonly reported reason for vaccination with Shingrix³ was “not applicable (prior to expansion of indications)” (80.8%, 6,225/7,707), followed by “age at the first vaccination with Shingrix (≥ 50 years)” (18.6%, 1,433/7,707), “immune function may be impaired by disease or treatment” (0.4%, 33/7,707) and “immune function impaired by disease or treatment” (0.4%, 31/7,707). The commonly reported reasons for vaccination with Shingrix in subjects under the age of 50 were “not applicable (prior to expansion of indications)” and “The physician's judgment that the vaccination with Shingrix was necessary for reasons other than the above” accounting for 0.8% (58/7,707) and 0.2% (18/7,707) of all subjects, respectively. (Table 2-2).

Table 3-1 shows the vaccination status and related data for first vaccination. Body temperature (°C) prior to vaccination with Shingrix was “ < 37.5 ” in 93.6% (7,211/7,707) of the doses and “unknown” in 6.4% (496/7,707). The sites of vaccination were “upper arm (right)” in 8.2% (629/7,707), “upper arm (left)” in 91.2% (7,028/7,707), “other (right)” in 0.0% (1/7,707), and “other (left)” in 0.6% (49/7,707). The routes of vaccination were “intramuscular” in 100.0% (7,706/7,707) and “other” in 0.0% (1/7,707). A detailed examination of the route of vaccination “other” (1) indicated that this subject had mistakenly received the first dose via subcutaneous injection, subsequently noticed an incorrect route of vaccination, and received the second dose via intramuscular injection. In this subject, “vaccination site swelling,” “vaccination site erythema,” “vaccination site pain,” “pyrexia,” and “fatigue” (1 event each) were reported as ADRs after the first vaccination; “vaccination site swelling,” “vaccination site erythema,” “vaccination site pain,” “pyrexia,” “chills,” “fatigue,” “myalgia,” and “headache” (1 event each) were reported after the second vaccination. All of these ADRs were non-serious and their outcomes were “resolved.”

Table 3-2 and Table 3-3 shows the vaccination statuses and related data on Shingrix at second and cumulative vaccinations, respectively, and these were generally similar to those for first vaccination.

³ The “reason for vaccination with Shingrix” was included as an investigation item in this investigation in connection with the approval for partial changes to approved matters granted in June 2023 with respect to the expansion of target population for vaccination to individuals aged ≥ 18 years, considered to be at high risk of herpes zoster. Therefore, information on the “reason for vaccination with Shingrix” is not collected from those whose information was collected before this approval for partial changes to approved matters (6,225).

2.4. Vaccines Administered Other Than Shingrix (Including Concomitantly Administered Vaccines)

Among the 7,707 subjects in the safety analysis set, those who received vaccines other than Shingrix, including concomitantly administered vaccines, by Day 30 after the first and second vaccinations with Shingrix (the day of vaccination with Shingrix is designated as Day 1) accounted for 2.9% (226/7,707) and 2.5% (189/7,464), respectively (Table 1-1). The vaccines administered were as shown in Table 4-1 (for the first vaccination) and Table 4.2 (for the second vaccination). The vaccines administered during the observation period for the first vaccination other than Shingrix included “influenza vaccine” (1.5%, 115/7,707), “COVID-19 vaccine” (0.9%, 66/7,707), “pneumococcal vaccine” (0.4%, 29/7,707) in descending order of frequency. The vaccines administered during the observation period for the second vaccination other than Shingrix included “COVID-19 vaccine” (1.4%, 101/7,464), “influenza vaccine” (1.0%, 78/7,464), and “pneumococcal vaccine” (0.1%, 11/7,464) in descending order of frequency.

2.5. Medications During Observation Period

Among the 7,707 subjects in the safety analysis set, 43.6% (3,362/7,707) received medications within 30 days after the first and second vaccinations with Shingrix (Table 1-1). The medications used during observation period were as shown in Table 5. By category, the most commonly reported medications used during observation period included “lipid-lowering agents” (14.8%, 1,142/7,707), “antihypertensives” (11.6%, 892/7,707), and “metabolic agents, not elsewhere classified” (9.9%, 764/7,707), in descending order of frequency. By medication, “amlodipine besilate” (6.6%, 512/7,707) was most commonly reported, followed by “rosuvastatin calcium” (5.1%, 392/7,707) and “methotrexate” (3.8%, 292/7,707).

2.6. Non-Drug Therapies Used During Observation Period

Among the 7,707 subjects in the safety analysis set, 0.7% (54/7,707) received non-drug therapies within 30 days after the first and second vaccinations with Shingrix (Table 1-1). Reported therapies were “surgery/other” (0.5%, 42/7,707) and “dialysis” (0.1%, 9/7,707) in descending order of frequency with CPAP (Continuous Positive Airway Pressure) being the most common therapies under “surgery/other”, as shown in Table 6.

2.7. Safety

2.7.1. Incidence of ADRs

ADRs were reported in 6,406 of the 7,707 subjects in the safety analysis set, and the percentage of subjects with ADRs was 83.1% (6,406/7,707) (Table 7-1, Attached Form 15).

By MedDRA SOC, ADRs classified under the “General disorders and administration site conditions” (82.6%, 6,365/7,707) were observed in the highest percentage of subjects, followed by those under the “Musculoskeletal and connective tissue disorders” (41.0%, 3,161/7,707) and the “Nervous system disorders” (33.3%, 2,564/7,707). The most commonly reported ADR was “vaccination site pain” (78.8%, 6,070/7,707), followed by “vaccination site swelling” (54.4%, 4,191/7,707) and “vaccination site erythema” (52.8%, 4,070/7,707).

In this investigation, local reactions (including injection site pain, injection site redness, and injection site swelling) and systemic reactions (including myalgia, fatigue, headache, chills, pyrexia, and gastrointestinal symptoms [nausea, vomiting, diarrhoea, and abdominal pain]) that occurred within 7 days after vaccination with Shingrix (by Day 7 with the day of vaccination as Day 1) were categorized as solicited adverse events (AE), whereas AEs, other than the solicited AEs, that occurred within 30 days after vaccination with Shingrix (by Day 30 with the day of vaccination as Day 1) were categorized as unsolicited AEs. Among the 7,707 subjects in the safety analysis set, the percentage of subjects with solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine were 83.0% (6,394/7,707) and 9.8% (754/7,707), respectively.

Serious ADRs were reported in 0.1% (5/7,707) of the 7,707 subjects in the safety analysis set.

Reported serious ADRs were “rheumatoid arthritis,” “melaena,” “retinal haemorrhage,” “internal haemorrhage,” and “hallucination” in 0.0% (1/7,707) each, and their outcomes were “resolving” or “resolved” (Table 7-2).

In this investigation, information on the severity of the reported AEs was also collected according to the severity (grade) classification of AEs shown in Table 7-3. The incidence proportion of ADRs by severity is shown in Table 7-4. Among the 7,707 subjects in the safety analysis set, the percentages of subjects with Grade 0, 1, 2, and 3 ADRs were 0.5% (37/7,707), 37.4% (2,881/7,707), 33.3% (2,567/7,707), and 11.6% (896/7,707), respectively. An analysis of solicited AEs that cannot be ruled out as being related to this vaccine by severity indicated that the percentages of subjects with Grade 0, 1, 2, and 3 solicited AEs were 0.5% (40/7,707), 37.5% (2,889/7,707), 33.2% (2,555/7,707), and 11.5% (885/7,707), respectively, and that the most commonly reported Grade 3 solicited AEs included “vaccination site erythema” (5.9%, 456/7,707), “vaccination site swelling” (4.7%, 362/7,707), and “vaccination site pain” (2.5%, 196/7,707). In addition, an analysis of unsolicited AEs that cannot be ruled out as being related to this vaccine by severity indicated that the percentages of subjects with Grade 0, 1, 2, and 3 unsolicited AEs were 0.0% (1/7,707), 7.1% (545/7,707), 2.1% (160/7,707), and 0.4% (34/7,707), respectively, and that the most commonly reported Grade 3 unsolicited AEs included “arthralgia” (0.1%, 9/7,707) and “dizziness” and “malaise” (0.0%, 3/7,707 each).

According to a pooled analysis of the global phase III studies (ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026), all of which were completed by the time of approval, the percentage of subjects with local and systemic solicited adverse events in the Shingrix group of the analysis set was 81.9% (5,360/6,544) and 53.1% (3,471/6,536), respectively (Attached Form 2-1). And the percentage of subjects with unsolicited adverse events that cannot be ruled out as being related to this vaccine was 31.4% (5,133/16,337) (Attached Form 2-2). Although a direct comparison is not feasible due to differences in subject characteristics and investigation method, the percentage of subjects with solicited and unsolicited adverse events that cannot be ruled out as being related to this vaccine in this investigation (83.0%, 6,394/7,707 and 9.8%, 754/7,707, respectively) were similar or lower than that of subjects with ADRs in the Shingrix group in the above pooled analysis of the global phase III studies (ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026). The most commonly reported ADRs in this investigation (such as “vaccination site pain,” “vaccination site swelling,” “vaccination site erythema,” “fatigue,” “myalgia,” “pyrexia,” “headache,” and “chills”) were similar to those reported by the time of approval. Compared with the pre-approval data, no new

safety concerns were identified regarding the incidence and types of ADRs reported in this investigation.

2.7.2. Incidence of ADRs by vaccination

2.7.2.1. Incidence of ADRs (the first vaccination)

ADRs were reported in 6,158 of the 7,707 doses in the safety analysis set (for the first vaccination) after the first vaccination, and the percentage of doses with ADRs after the first vaccination was 79.9% (6,158/7,707) (Table 8-1).

By SOC, ADRs classified under the “General disorders and administration site conditions” (79.1%, 6,095/7,707) were observed in the highest percentage of doses, followed by those under the “Musculoskeletal and connective tissue disorders” (30.6%, 2,357/7,707) and the “Nervous system disorders” (22.9%, 1,762/7,707). The most commonly reported ADR was “vaccination site pain” (74.2%, 5,716/7,707), followed by “vaccination site swelling” (42.5%, 3,274/7,707) and “vaccination site erythema” (40.7%, 3,136/7,707).

The percentages of doses who experienced solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine after the first vaccination were 79.6% (6,137/7,707) and 7.0% (542/7,707), respectively.

As a serious ADR after the first vaccination, “internal haemorrhage” (1) was reported.

The incidence proportion of ADRs by severity after the first vaccination is shown in Table 8-2.

Among the 7,707 doses in the safety analysis set, the percentages of doses with Grade 0, 1, 2, and 3 ADRs were 0.6% (46/7,707), 45.6% (3,515/7,707), 26.5% (2,043/7,707), and 6.6% (509/7,707), respectively. An analysis of solicited AEs that cannot be ruled out as being related to this vaccine by severity after the first vaccination indicated that the percentages of doses with Grade 0, 1, 2, and 3 solicited AEs were 0.6% (48/7,707), 45.6% (3,515/7,707), 26.2% (2,023/7,707), and 6.5% (504/7,707), respectively, and that the most commonly reported Grade 3 solicited AEs included “vaccination site erythema” (3.1%, 237/7,707), “vaccination site swelling” (2.4%, 182/7,707), and “vaccination site pain” (1.5%, 118/7,707). In addition, an analysis of unsolicited AEs by severity after the first vaccination indicated that the percentages of doses with Grade 0, 1, 2, and 3 unsolicited AEs were 0.0% (0/7,707), 5.3% (407/7,707), 1.3% (103/7,707), and 0.3% (20/7,707), respectively, and that the most commonly reported Grade 3 unsolicited AEs included “arthralgia” (0.1%, 6/7,707) and “dizziness” and “malaise” (0.0%, 2/7,707 each).

2.7.2.2. Incidence of ADRs (the second vaccination)

ADRs were reported after the second vaccination in 5,574 of the 7,464 doses in the safety analysis set (for the second vaccination), and the percentage of doses with ADRs after the second vaccination was 74.7% (5,574/7,464) (Table 8-3).

As is the case with the first vaccination, by SOC, ADRs classified under the “General disorders and administration site conditions” (74.2%, 5,542/7,464) were observed in the highest percentage of doses, followed by those under the “Musculoskeletal and connective tissue disorders” (29.0%, 2,163/7,464) and the “Nervous system disorders” (24.5%, 1,829/7,464). Also similar to the first vaccination, the most commonly reported ADR was “vaccination site pain” (68.2%, 5,088/7,464), followed by

“vaccination site swelling” (44.2%, 3,298/7,464) and “vaccination site erythema” (41.7%, 3,109/7,464).

The percentages of doses who experienced solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine after the second vaccination were 74.5% (5,559/7,464) and 4.9% (369/7,464), respectively.

Serious ADRs reported after the second vaccination were “rheumatoid arthritis,” “melaena,” “retinal haemorrhage,” and “hallucination” (1 each).

The incidence proportion of ADRs by severity after the second vaccination is shown in Table 8-4.

Among the 7,464 doses in the safety analysis set (for the second vaccination), the percentages of doses with Grade 0, 1, 2, and 3 ADRs were 1.0% (72/7,464), 41.2% (3,074/7,464), 24.4% (1,821/7,464), and 7.5% (560/7,464), respectively. An analysis of solicited AEs by severity after the second vaccination indicated that the percentages of doses with Grade 0, 1, 2, and 3 solicited AEs were 1.0% (73/7,464), 41.2% (3,075/7,464), 24.2% (1,810/7,464), and 7.4% (554/7,464), respectively, and that the most commonly reported Grade 3 solicited AEs included “vaccination site erythema” (3.8%, 281/7,464), “vaccination site swelling” (3.1%, 231/7,464), and “fatigue” (1.4%, 107/7,707). In addition, an analysis of unsolicited AEs that cannot be ruled out as being related to this vaccine by severity after the second vaccination indicated that the percentages of doses with Grade 0, 1, 2, and 3 unsolicited AEs were 0.0% (1/7,464), 3.6% (268/7,464), 1.0% (78/7,464), and 0.2% (15/7,464), respectively, and that the most commonly reported Grade 3 unsolicited AE was “arthralgia” (0.0%, 3/7,464).

2.7.2.3. Incidence of ADRs (cumulative vaccination)

ADRs were reported in 11,732 of the 15,171 doses in the safety analysis set (for all vaccinations combined); the percentage of doses with ADRs was 77.3% (11,732/15,171) (Table 8-5).

By SOC, ADRs classified under the “General disorders and administration site conditions” (76.7%, 11,637/15,171) were observed in the highest percentage of doses, followed by those under the “Musculoskeletal and connective tissue disorders” (29.8%, 4,520/15,171) and the “Nervous system disorders” (23.7%, 3,591/15,171). The most commonly reported ADR was “vaccination site pain” (71.2%, 10,804/15,171), followed by “vaccination site swelling” (43.3%, 6,572/15,171) and “vaccination site erythema” (41.2%, 6,245/15,171).

The percentages of doses with solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine were 77.1% (11,696/15,171) and 6.0% (911/15,171), respectively, for all vaccinations combined.

Serious ADRs reported across all vaccinations were “rheumatoid arthritis,” “melaena,” “internal haemorrhage,” “retinal haemorrhage,” and “hallucination” (1 each).

The incidence proportion of ADRs by severity is shown in Table 8-6. Among the 15,171 doses in the safety analysis set (for all vaccinations combined), the percentages of doses with Grade 0, 1, 2, and 3 ADRs were 0.8% (118/15,171), 43.4% (6,589/15,171), 25.5% (3,864/15,171), and 7.0% (1,069/15,171), respectively. An analysis of solicited AEs that cannot be ruled out as being related to this vaccine by severity for all vaccinations combined indicated that the percentages of doses with Grade 0, 1, 2, and 3 solicited AEs were 0.8% (121/15,171), 43.4% (6,590/15,171), 25.3% (3,833/15,171), and 7.0% (1,058/15,171), respectively, and that the most commonly reported Grade 3 solicited AEs included “vaccination site erythema” (3.4%, 518/15,171), “vaccination site swelling”

(2.7%, 413/15,171), and “vaccination site pain” (1.4%, 219/15,171). In addition, an analysis of unsolicited AEs that cannot be ruled out as being related to this vaccine by severity for all vaccinations combined indicated that the percentages of doses with Grade 0, 1, 2, and 3 unsolicited AEs were 0.0% (1/15,171), 4.4% (675/15,171), 1.2% (181/15,171), and 0.2% (35/15,171), respectively, and that the most commonly reported Grade 3 unsolicited AEs included “arthralgia” (0.1%, 9/15,171) and “dizziness” and “malaise” (0.0%, 3/15,171 each).

2.7.3. Time to onset of ADRs

2.7.3.1. Time to onset of ADRs after the first vaccination

Among the 7,707 doses in the safety analysis set (for the first vaccination), 6,158 doses experienced ADRs, and the time to onset of ADRs from the day of vaccination with Shingrix was analyzed by type of ADR. As shown in Table 9-1, the analysis indicated that 85.5% (5,249/6,137) of the ADRs classified as solicited AEs were observed on Day 1 of the vaccination (the day of vaccination), and 99.0% (6,075/6,137) by Day 2. With respect to ADRs classified as unsolicited AEs, 91.5% (496/542) were observed by Day 7. No other notable trends were observed.

2.7.3.2. Time to onset of ADRs after the second vaccination

Among the 7,464 doses in the safety analysis set (for the second vaccination), 5,574 doses experienced ADRs, and the time to onset of ADRs from the day of vaccination with Shingrix was analyzed by type of ADR. As shown in Table 9-2, the analysis indicated that 86.5% (4,811/5,559) of ADRs classified as solicited AEs were observed on Day 1 of the vaccination (the day of vaccination), and 99.5% (5,532/5,559) by Day 2. With respect to ADRs classified as unsolicited AEs, 92.7% (342/369) were observed by Day 7. The time to onset of ADRs after the second vaccination showed a similar trend to that after the first vaccination, and no other notable trends were observed.

2.7.4. Factors affecting the onset of ADRs

In order to examine factors affecting the onset of ADRs, univariate and multivariate logistic regression analyses were performed by subject characteristics in the safety analysis set consisting of 7,707 subjects.

In the univariate logistic regression analysis, factors meeting the following criteria were examined: the point estimate was > 2 or < 0.5 for the unadjusted odds ratio in the incidence proportion of ADRs by subject characteristics; and the asymptotic 95% confidence interval does not exceed 1. As a result, as shown in Table 10-1, “immune abnormality,” “underlying disease associated with immune abnormality,” “prior medication (that may affect the immune system),” “underlying disease,” and “underlying disease (other)” met the above criteria.

In the multivariate logistic regression analysis, the following factors were used as explanatory variables, taking into account correlations between variables (Table 10-2): “sex,” “age 1” (< 15 years, ≥ 15 years and < 50 years, ≥ 50 years and < 65 years, ≥ 65 years and < 75 years, and ≥ 75 years), “history of vaccination with herpes zoster vaccines other than Shingrix,” “history of

herpes zoster,” “immune abnormality,” “underlying disease,” and “past medical history⁴.” As shown in Table 10-3, the results of the multivariate analysis indicated that “age 1” and “underlying disease” met the above criteria. The factors “age 1” and “underlying disease,” which met certain criteria in the multivariate logistic regression analysis, were examined as described in the following sections.

2.7.4.1. Age 1 (< 15 years, ≥ 15 years and < 50 years, ≥ 50 years and < 65 years, ≥ 65 years and < 75 years, and ≥ 75 years)

The percentage of subjects with ADRs in the age group “≥ 15 and < 50 years”, “≥ 50 and < 65 years”, “≥ 65 and < 75 years” and “≥ 75 years” were 87.3% (69/79), 84.9% (2,628/3,096), 83.9% (1,882/2,243), 76.3% (1,141/1,495), respectively. The incidence proportion of ADRs was lower in the age group “≥ 75 years” than in the age group “≥ 50 and < 65 years” (point estimate of adjusted odds ratio, 0.448; 95% confidence interval, 0.381-0.527) (Table 10-3). The incidence proportion of ADRs was examined by age group. As shown in Table 11-1, the percentages of subjects with solicited AEs such as “vaccination site pain,” “vaccination site swelling,” “vaccination site erythema”, “fatigue” and “pyrexia” were lower in the age group “≥ 75 years” than in the age group “≥ 50 years and < 65 years.” It is known that the occurrence of adverse reactions after vaccination is influenced by multiple factors such as the characteristics of the recipient and the vaccine, and the method of administration [Hervé, 2019], among which age is considered one of the particularly important factors. It is reported that the inflammatory immune response in the acute phase after vaccination is reduced in elderly people [Yousfi, 2005], and this may have been a factor in the lower percentage of subjects with ADRs in the age group “≥ 75 years.”

2.7.4.2. Underlying disease

The percentage of subjects with ADRs in the groups with and without underlying diseases were 87.6% (2,998/3,423) and 78.0% (2,722/3,490), respectively. The percentage of subjects with ADRs was higher in those with underlying diseases than in those without (point estimate of adjusted odds ratio, 2.099; 95% confidence interval, 1.821-2.419) (Table 10-3). The incidence proportion of ADRs was examined by the presence or absence of underlying diseases. As shown in Table 11-2, the percentages of subjects with solicited AEs such as “vaccination site pain,” “vaccination site swelling,” and “vaccination site erythema” were higher in those with underlying diseases than in those without. As shown in Table 1-5, the most commonly reported underlying diseases in the safety analysis set of this investigation included “hypertension” (22.2%, 1,710/7,707), “dyslipidaemia” in (9.0%, 691/7,707), and “rheumatoid arthritis” (6.9%, 530/7,707). A prior study of ADRs to COVID vaccination among individuals with one of these most commonly reported comorbidities, rheumatoid arthritis and among those with systemic lupus erythematosus found they were at higher risk of vaccination site pain, swelling, and redness after COVID-19 vaccination than healthy individuals [Bartels, 2021]. In fact, the percentage of ADRs in subjects with comorbid rheumatoid arthritis was found to be as high as 90.4% (479/530) in this investigation. Therefore, the higher percentage of ADRs in subjects with underlying diseases might be considered partly attributable to the fact that vaccination site reactions in the acute phase after vaccination with Shingrix were commonly reported in patients with autoimmune

⁴ Diseases diagnosed prior to vaccination that had resolved before the time of vaccination.

diseases such as rheumatoid arthritis, but another report suggests that the occurrence of adverse events after COVID-19 vaccination is unrelated to the presence or absence of underlying conditions [Frankenthal, 2025]. The exact reason was unclear. All ADRs of “vaccination site pain,” “vaccination site swelling,” and “vaccination site erythema” reported in this investigation were non-serious, and their outcomes were “resolved” or “resolving” except for one with unknown outcome (Table 7-2). Therefore, it was considered unnecessary to implement new measures to ensure proper use of Shingrix for the safety of individuals with underlying diseases.

2.7.5. Incidence of ADRs in subjects receiving concomitant immune checkpoint inhibitors

Since patients with malignant tumors were not included in the clinical studies completed by the time of approval of Shingrix, no information on Shingrix subjects who concomitantly used immune checkpoint inhibitors had been obtained. Among the 7,707 subjects in the safety analysis set in this investigation, underlying diseases classified under the System Organ Class (SOC) “Neoplasms benign, malignant and unspecified (incl cysts and polyps)” were reported in 2.3% (179/7,707) of the subjects (Table 1-5), and use of the immune checkpoint inhibitors “atezolizumab (genetical recombination)” and “durvalumab (genetical recombination)” was reported in one subject each (Table 5). ADRs were reported in both subjects and the reported ADRs were “vaccination site erythema,” “vaccination site pain,” and “vaccination site swelling” (1 each). All of them were non-serious, and their outcomes were “resolved.” Although the number of subjects receiving immune checkpoint inhibitors in this investigation was limited, no new concerns were identified regarding the safety of Shingrix in them.

2.7.6. AEs or ADRs of special interest

Among the risks specified in the Risk Management Plan of Shingrix [GSK, 2026], “shock and anaphylaxis” and “potential immune-mediated disease” were identified as the AEs or ADRs of special interest in this investigation, and the incidence proportion of ADRs associated with the AEs or ADRs of special interest in the 7,707 subjects in the safety analysis set were examined (Attached Form 12). As ADRs associated with “shock and anaphylaxis,” Preferred Terms (PTs) within the Standardized MedDRA Query (SMQ) for “anaphylactic reaction” (narrow) and “hypersensitivity” (narrow) were tabulated (Table 12). As ADRs associated with “potential immune-mediated disease,” PTs within MedDRA SMQ for “immune-mediated/autoimmune disorders” (broad) and “demyelination” (broad) were tabulated.

The results of examination on the AEs or ADRs of special interest “shock and anaphylaxis” and “potential immune-mediated disease” are shown below.

2.7.6.1. Shock and anaphylaxis

Table 13-1 shows the incidence proportion of ADRs associated with “shock and anaphylaxis” in the 7,707 subjects in the safety analysis set. ADRs associated with “shock and anaphylaxis” were reported in 55 subjects, 0.7% (55/7,707) of the safety analysis set. The most commonly reported ADRs included “rash” (0.3%, 21/7,707), “urticaria” (0.2%, 15/7,707), and “eczema” (0.1%, 9/7,707), in descending order of frequency. No serious ADRs were reported. The outcomes of all ADRs associated with “shock and anaphylaxis” were “resolved” or “resolving” except for one with unknown outcome (Table 13-2). The timing of ADRs occurrence associated with “shock and anaphylaxis” and the

background of the vaccinated subjects who experienced these ADRs were as shown in Table 13-3. One of the essential criteria for anaphylaxis according to the Brighton collaboration case definition are rapid progression of signs and symptoms which typically affect multiple body systems (skin/mucosa/respiratory/cardiovascular/gastrointestinal) at the same time or sequentially [Gold, 2023]. However, as shown in Table 13-3, all reported events in this study were limited to skin/mucosal symptoms, and no subjects experienced symptoms in multiple body systems. Therefore, it was considered that there were no subjects that met the criteria for anaphylaxis symptoms based on the Brighton collaboration case definition.

According to a pooled analysis of the global phase III study in subjects aged ≥ 50 years (Study ZOSTER-006) and the global phase III study in subjects aged ≥ 70 years (Study ZOSTER-022), both of which were completed by the time of approval, in the Shingrix group, unsolicited AEs within MedDRA SMQ for “hypersensitivity” (narrow) occurring within 30 days after vaccination were reported in 2.6% (380/14,645) of the subjects, whereas AEs within MedDRA SMQ for “anaphylactic reaction” (narrow) were reported in 0.0% (1/14,645) [data on file, CTD 2.7.4-p99]. Although a direct comparison is not feasible due to differences in subject characteristics, investigation method and assessment method, the percentage of subjects with ADRs associated with “shock and anaphylaxis” in this investigation was lower at 0.7% (55/7,707) when compared with that of subjects reported by the time of approval; no new concerns were identified regarding the incidence, types, or outcomes of ADRs associated with “shock and anaphylaxis” in this investigation.

2.7.6.2. Incidence of potential immune-mediated disease

Table 14-1 shows the incidence proportion of ADRs associated with “potential immune-mediated disease” in the 7,707 subjects in the safety analysis set. ADRs associated with “potential immune-mediated disease” were reported in 2 subjects (0.0%, 2/7,707). The most commonly reported ADRs were “butterfly rash” and “rheumatoid arthritis” (0.0%, 1/7,707 each). Of these, “rheumatoid arthritis” (0.0%, 1/7,707) was a serious ADR (Table 14-2). PPD experienced a “butterfly rash” the day after receiving the second dose of this vaccine, which resolved five days later. PPD, who had a pre-existing condition of rheumatoid arthritis, experienced a worsening of rheumatoid arthritis on the day of the second dose, which resolving 83 days later. Based on information such as the results of a post-marketing observational study (Study EPI-ZOSTER-032) conducted in the US, the status of data collection for spontaneous reports in the safety information database, and published literature, “Guillain-Barre syndrome” was newly added as an important identified risk in J-Risk Management Plan in February 2026 [GSK, 2026]; Guillain-Barre syndrome was previously included as an important potential risk in the Risk Management Plan of Shingrix and had been evaluated as part of the “potential immune-mediated disease.” However, no ADRs associated with Guillain-Barre syndrome were reported in this investigation.

In a pooled analysis of the global phase III study in subjects aged ≥ 50 years (Study ZOSTER-006) and the global phase III study in subjects aged ≥ 70 years (Study ZOSTER-022), both of which were completed by the time of approval, potential immune-mediated diseases that the investigator considered to be related to vaccination were reported in 0.1% (16/14,645) of the subjects in the Shingrix group throughout the follow-up period after vaccination [data on file, CTD 2.7.4-p92]. Although a direct comparison is not feasible due to differences in subject characteristics, investigation

method and assessment method, the percentage of subjects with ADRs associated with “potential immune-mediated disease” in this investigation was 0.0% (2/7,707), which was similar to that of subjects reported by the time of approval, and no new concerns were identified regarding the incidence, types, or outcomes of ADRs associated with “potential immune-mediated disease” in this investigation.

2.8. Individuals with Specific Characteristics

Regarding safety in individuals with special characteristics, the following were observed.

2.8.1.1. Children (< 15 years)

The intended subjects of Shingrix are those aged ≥ 18 years who are considered to be at high risk of herpes zoster [GSK, 2025]; among the 7,707 subjects in the safety analysis set, no use in children (< 15 years) was reported (Table 1-1).

2.8.1.2. Elderly people (≥ 65 years)

Among the 7,707 subjects in the safety analysis set, use in elderly people (≥ 65 years) was reported in 54.6% (4,210/7,707) (Table 1-1). The percentage of elderly subjects with ADRs was 81.4% (3,429/4,210), whereas those with solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine were 81.3% (3,421/4,210) and 7.7% (325/4,210), respectively (Table 15). In elderly subjects, the most commonly reported solicited AEs included “vaccination site pain” (76.6%, 3,225/4,210), “vaccination site swelling” (53.8%, 2,264/4,210), and “vaccination site erythema” (52.9%, 2,225/4,210), whereas the most commonly reported unsolicited AEs were “vaccination site pruritus” (2.2%, 94/4,210), “pruritus” (1.1%, 47/4,210), and “arthralgia” (0.6%, 27/4,210) (Table 16-1). As serious ADRs, “rheumatoid arthritis” and “retinal haemorrhage” (0.0%, 1/4,210 each) were reported. The outcomes of all ADRs reported in elderly subjects were “resolved” or “resolving” except for one with unknown outcome (Table 16-2). The percentage of elderly subjects with ADRs was 81.4% (3,429/4,210), whereas that of subjects aged < 65 years with ADRs was 85.1% (2,977/3,497); both were similar. As described in the section “2.7.4.1. Age 1 (< 15 years, ≥ 15 years and < 50 years, ≥ 50 years and < 65 years, ≥ 65 years and < 75 years, and ≥ 75 years)”, in the multivariate logistic regression analysis, the incidence proportion of ADRs was lower in the age group “ ≥ 75 years” than in the age group “ ≥ 50 and < 65 years” (point estimate of adjusted odds ratio, 0.448; 95% confidence interval, 0.381-0.527) (Table 10 3). It is reported that the inflammatory immune response in the acute phase after vaccination is reduced in elderly people [Yousfi, 2005], and this may have been a factor in the lower percentage of subjects with ADRs in the age group “ ≥ 75 years.” Based on the above, no tendency was observed for a higher incidence of adverse reactions in elderly people, and no new concerns regarding the safety of Shingrix were identified in elderly people.

2.8.1.3. Pregnant and breastfeeding women

Among the 7,707 subjects in the safety analysis set, use in women was reported in 67.6% (5,212/7,707); no use was reported in pregnant and breastfeeding women (Table 1-1).

2.8.1.4. Individuals with renal impairment

Among the 7,707 subjects in the safety analysis set, use in individuals with renal impairment was reported in 1.4% (110/7,707) (Table 1-1). The percentage of subjects with renal impairment who experienced ADRs was 82.7% (91/110), whereas those of subjects with renal impairment who experienced solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine were 81.8% (90/110) and 12.7% (14/110), respectively (Table 15). In subjects with renal impairment, the most commonly reported solicited AEs were “vaccination site pain” (75.5%, 83/110), “vaccination site swelling” (44.5%, 49/110), and “vaccination site erythema” (42.7%, 47/110), whereas the most commonly reported unsolicited AEs were “vaccination site pruritus” (5.5%, 6/110), “chills,” “swelling,” “muscle spasms,” “dysgeusia,” “toothache,” “constipation,” “lip swelling,” “pruritus,” “urticaria,” “blister,” “scab,” “rhinorrhoea,” and “lymphadenopathy” (0.9%, 1/110 each). All ADRs reported in subjects with renal impairment were non-serious, and no serious ADRs were reported (Table 17-1). The outcomes of all ADRs in subjects with renal impairment were “resolved” or “resolving” (Table 17-2). The percentage of subjects with renal impairment who experienced ADRs (82.7%, 91/110) was comparable to that of subjects without renal impairment who experienced ADRs (83.1%, 6,315/7,597); no new concerns were identified regarding the safety of Shingrix in individuals with renal impairment.

2.8.1.5. Individuals with hepatic impairment

Among the 7,707 subjects in the safety analysis set, use in individuals with hepatic impairment was reported in 2.2% (166/7,707) (Table 1-1). The percentage of subjects with hepatic impairment who experienced ADRs was 85.5% (142/166), whereas those of subjects with hepatic impairment who experienced solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine were 85.5% (142/166) and 18.7% (31/166), respectively (Table 15). In subjects with hepatic impairment, the most commonly reported solicited AEs were “vaccination site pain” (81.3%, 135/166) and “vaccination site swelling” and “vaccination site erythema” (56.6%, 94/166 each), whereas the most commonly reported unsolicited AEs were “vaccination site pruritus” (5.4%, 9/166), “pruritus” (4.8%, 8/166), and “malaise” (3.0%, 5/166). All ADRs reported in subjects with hepatic impairment were non-serious, and no serious ADRs were reported (Table 18-1). The outcomes of all ADRs in subjects with hepatic impairment were “resolved” or “resolving” (Table 18-2). The percentage of subjects with hepatic impairment who experienced ADRs (85.5%, 142/166) was comparable to that of subjects without hepatic impairment who experienced ADRs (83.1%, 6,264/7,541); no new concerns were identified regarding the safety of Shingrix in subjects with hepatic impairment.

2.8.1.6. Individuals with immune abnormalities

Among the 7,707 subjects in the safety analysis set, use in individuals with immune abnormalities⁵ was reported in 9.1% (702/7,707); the percentages of subjects with underlying diseases associated with immune abnormalities, prior medications (that may affect the immune system), and prior therapies (that may affect the immune system) were 8.7% (672/7,707), 8.2% (635/7,707), and 0.1%

⁵ Individuals with abnormal immune status due to underlying diseases associated with immune abnormalities, prior medications, or prior therapies

(8/7,707), respectively (multiple responses allowed) (see Table 1-1, “2.2. Subject Characteristics [Distribution]”). The percentage of subjects with immune abnormalities who experienced ADRs was 90.6% (636/702), whereas those of subjects with immune abnormalities who experienced solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine were 90.6% (636/702) and 16.4% (115/702), respectively (Table 15). In subjects with immune abnormalities, the most commonly reported solicited AEs were “vaccination site pain” (85.5%, 600/702), “vaccination site erythema” (63.1%, 443/702), and “vaccination site swelling” (63.0%, 442/702), whereas the most commonly reported unsolicited AEs were “vaccination site pruritus” (5.6%, 39/702), “pruritus” (4.1%, 29/702), and “arthralgia” (1.7%, 12/702). As a serious ADR, “rheumatoid arthritis” (0.1%, 1/702) was reported (Table 19-1). The outcomes of all ADRs reported in subjects with immune abnormalities were “resolved” or “resolving” (Table 19-2). As a result of the multivariate logistic regression analysis, among the 7,707 subjects in the safety analysis set, the incidence proportion rate of ADRs in the subjects with and without immune abnormalities were 90.8% (513/565) and 82.0% (5,207/6,348), respectively, and “immune abnormality” did not meet the above criteria (point estimate of adjusted odds ratio, 1.331; 95% confidence interval, 0.976-1.814) (Table 10-3). Therefore, no new concerns were identified regarding the safety of Shingrix in subjects with immune abnormalities.

2.8.1.7. Individuals considered to require precaution for vaccination by the investigator

Among the 7,707 subjects in the safety analysis set, use in individuals considered to require precaution for vaccination by the investigator was reported in 0.5% (39/7,707) (Table 1-1). As the result of the univariate logistic regression analysis, the incidence proportion rates of ADRs in those classified as "Applicable" and "Not Applicable" for individuals considered to require precaution for vaccination by the investigator were 92.3% (36/39 cases) and 83.1% (6,370/7,668 cases), respectively, and did not meet the above criteria (point estimate of unadjusted odds ratio: 2.445, 95% confidence interval: 0.752-7.950) (Table 10-1).

3. Summary

3.1. Safety Summary

ADRs were reported in 6,406 of the 7,707 subjects in the safety analysis set of the drug use investigation, and the percentage of subjects with ADRs was 83.1% (6,406/7,707). By MedDRA SOC, ADRs classified under the “General disorders and administration site conditions” (82.6%, 6,365/7,707) were observed in the highest percentage of subjects, followed by those under the “Musculoskeletal and connective tissue disorders” (41.0%, 3,161/7,707) and the “Nervous system disorders” (33.3%, 2,564/7,707). The most commonly reported ADR was “vaccination site pain” (78.8%, 6,070/7,707), followed by “vaccination site swelling” (54.4%, 4,191/7,707) and “vaccination site erythema” (52.8%, 4,070/7,707). Serious ADRs were reported in 0.1% (5/7,707) of the 7,707 subjects in the safety analysis set. Reported serious ADRs were “rheumatoid arthritis,” “melaena,” “retinal haemorrhage,” “internal haemorrhage,” and “hallucination” (0.0%, 1/7,707 each), and their outcomes were “resolving” or “resolved.” The percentages of subjects with solicited and unsolicited AEs that cannot be ruled out as being related to this vaccine in the 7,707 subjects in the safety analysis set were 83.0% (6,394/7,707) and 9.8% (754/7,707), respectively. Examination of the incidence

proportion of ADRs by severity indicated that the incidence proportion of Grade 3 ADRs in the 7,707 subjects in the safety analysis set was 11.6% (896/7,707). According to a pooled analysis of the global phase III study (StudyZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026), all of which were completed by the time of approval, the percentage of subjects with local and systemic solicited adverse events in the Shingrix group of the analysis set was 81.9% (5,360/6,544) and 53.1% (3,471/6,536), respectively (Attached Form 2-1). And the percentage of subjects with unsolicited adverse events that cannot be ruled out as being related to this vaccine was 31.4% (5,133/16,337) (Attached Form 2-2). Although a direct comparison is not feasible due to differences in subject characteristics and investigation method, the percentage of subjects with solicited and unsolicited adverse events that cannot be ruled out as being related to this vaccine in this investigation (83.0%, 6,394/7,707 and 9.8%, 754/7,707, respectively) were not higher than that of subjects with ADRs in the Shingrix group in the above pooled analysis of the global phase III studies (ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026). The most commonly reported ADRs in this investigation (such as “vaccination site pain,” “vaccination site swelling,” “vaccination site erythema,” “fatigue,” “myalgia,” “pyrexia,” “headache,” and “chills”) were similar to those reported by the time of approval. Compared with the pre-approval data, no new safety concerns were identified regarding the incidence and types of ADRs reported in this investigation.

In addition, the time to onset of ADRs after vaccination with Shingrix was measured for each vaccination. After the first vaccination, 6,158 of the 7,707 doses in the safety analysis set (for the first vaccination) reported ADRs; regarding the solicited AEs that cannot be ruled out as being related to this vaccine, 85.5% (5,249/6,137) of the subjects with ADRs experienced the ADRs on Day 1 (the day of vaccination), and 99.0% (6,075/6,137) by Day 2. With respect to ADRs classified as unsolicited AEs, 91.5% (496/542) were observed by Day 7. The time to onset of ADRs after the second vaccination showed a similar trend to that after the first vaccination, and no other notable trends were observed.

In order to examine factors affecting the onset of ADRs, univariate and multivariate logistic regression analyses were performed by subject characteristics in the 7,707 subjects in the safety analysis set. The results of the multivariate analysis indicated that “age 1” (< 15 years, ≥ 15 years and < 50 years, ≥ 50 years and < 65 years, ≥ 65 years and < 75 years, and ≥ 75 years) and “underlying disease” met the criteria: the point estimate was > 2 or < 0.5 for the adjusted odds ratio in the incidence proportion of ADRs by subject characteristics and the asymptotic 95% confidence interval does not exceed 1. Regarding “age 1”, The incidence proportion of ADRs was lower in the age group “≥ 75 years” than in the age group “≥ 50 and < 65 years” (point estimate of adjusted odds ratio, 0.448; 95% confidence interval, 0.381-0.527). The percentages of subjects with solicited AEs such as “vaccination site pain,” “vaccination site swelling,” “vaccination site erythema,” “fatigue” and “pyrexia” were lower in the age group “≥ 75 years” than in the age group “≥ 50 years and < 65 years.” It is known that the occurrence of adverse reactions after vaccination is influenced by multiple factors such as the characteristics of the recipient and the vaccine, and the method of administration [Hervé, 2019], among which age is considered one of the particularly important factors. It is reported that the inflammatory immune response in the acute phase after vaccination is reduced in elderly people [Yousfi, 2005], and this may have been a factor in the lower percentage of subjects with ADRs in the age group “≥ 75 years.” Regarding “underlying disease”, the percentage of subjects with ADRs was

higher in those with underlying diseases than in those without (point estimate of adjusted odds ratio, 2.099; 95% confidence interval, 1.821-2.419). The percentages of subjects with solicited AEs such as “vaccination site pain,” “vaccination site swelling,” and “vaccination site erythema” were higher in those with underlying diseases than in those without. The most commonly reported underlying diseases in the safety analysis set of this investigation included “hypertension” (22.2%, 1,710/7,707), “dyslipidaemia” in (9.0%, 691/7,707), and “rheumatoid arthritis” (6.9%, 530/7,707). A prior study of ADRs to COVID vaccination among individuals with one of these most commonly reported comorbidities, rheumatoid arthritis and among those with systemic lupus erythematosus found they were at higher risk of vaccination site pain, swelling, and redness after COVID-19 vaccination than healthy individuals [Bartels, 2021]. In fact, the percentage of ADRs in subjects with comorbid rheumatoid arthritis was found to be as high as 90.4% (479/530) in this investigation. Therefore, the higher percentage of ADRs in subjects with underlying diseases might be considered partly attributable to the fact that vaccination site reactions in the acute phase after vaccination with Shingrix were commonly reported in patients with autoimmune diseases such as rheumatoid arthritis. But another report suggests that the occurrence of adverse events after COVID-19 vaccination is unrelated to the presence or absence of underlying conditions [Frankenthal, 2025]. The exact reason was unclear. In this investigation, 2 subjects were reported to use immune checkpoint inhibitors (atezolizumab and durvalumab), a therapy for which safety of Shingrix could not be sufficiently evaluated by the time of approval. Although ADRs were reported in both subjects, no new concerns were identified regarding the safety of Shingrix in individuals receiving immune checkpoint inhibitors.

In this investigation, the incidence proportions of ADRs associated with “shock and anaphylaxis” and “potential immune-mediated disease” were examined as AEs or ADRs of special interest. In the 7,707 subjects in the safety analysis set, ADRs associated with “shock and anaphylaxis” were reported in 55 subjects (0.7%, 55/7,707). The most commonly reported ADRs included “rash” (0.3%, 21/7,707), “urticaria” (0.2%, 15/7,707), and “eczema” (0.1%, 9/7,707), in descending order of frequency. No serious ADRs were reported. The outcomes of all ADRs associated with “shock and anaphylaxis” were “resolved” or “resolving” except for one with unknown outcome. According to a pooled analysis of the global phase III study in subjects aged ≥ 50 years (Study ZOSTER-006) and the global phase III study in subjects aged ≥ 70 years (Study ZOSTER-022), both of which were completed by the time of approval, in the Shingrix group, unsolicited AEs within MedDRA SMQ for “hypersensitivity” (narrow) occurring within 30 days after vaccination were reported in 2.6% (380/14,645) of the subjects, whereas AEs within MedDRA SMQ for “anaphylactic reaction” (narrow) were reported in 0.0% (1/14,645). Although a direct comparison is not feasible due to differences in subject characteristics, investigation method and assessment method, the percentage of subjects with ADRs associated with “shock and anaphylaxis” in this investigation was lower at 0.7% (55/7,707) when compared with that of subjects reported by the time of approval; no new concerns were identified regarding the incidence, types, or outcomes of ADRs associated with “shock and anaphylaxis” in this investigation.

In the 7,707 subjects in the safety analysis set, ADRs associated with “potential immune-mediated disease” were reported in 2 subjects (0.0%, 2/7,707). The most commonly reported ADRs were “butterfly rash” and “rheumatoid arthritis” (0.0%, 1/7,707 each). In a pooled analysis of the global phase III study in subjects aged ≥ 50 years (Study ZOSTER-006) and the global phase III study in

subjects aged ≥ 70 years (Study ZOSTER-022), both of which were completed by the time of approval, the “potential immune-mediated diseases” that the investigator considered to be related to vaccination were reported in 0.1% (16/14,645) of the subjects in the Shingrix group throughout the follow-up period after vaccination. Although a direct comparison is not feasible due to differences in subject characteristics, investigation method and assessment method, the percentage of subjects with ADRs associated with “potential immune-mediated disease” in this investigation was 0.0% (2/7,707), which was similar to that of subjects reported by the time of approval, and no new concerns were identified regarding the incidence, types, or outcomes of ADRs associated with “potential immune-mediated disease” in this investigation.

As individuals with specific characteristics, the percentages of children (< 15 years), elderly people (≥ 65 years), pregnant and breastfeeding women, individuals with renal impairment, individuals with hepatic impairment, individuals with immune abnormalities and individuals considered to require precaution for vaccination by the investigator who experienced ADRs were examined. In the 7,707 subjects in the safety analysis set of this investigation, no use in children (< 15 years) was reported. Use in elderly people (≥ 65 years) was reported in 54.6% (4,210/7,707). The percentage of elderly subjects with ADRs was 81.4% (3,429/4,210). The percentage of elderly subjects with ADRs was 81.4% (3,429/4,210), whereas that of subjects aged < 65 years with ADRs was 85.1% (2,977/3,497); both were similar. and no new concerns were identified regarding the safety of Shingrix in elderly people. Use in women was reported in 67.6% (5,212/7,707); no use was reported in pregnant and breastfeeding women. Use in individuals with renal impairment was reported in 1.4% (110/7,707) and the percentage of subjects with renal impairment who experienced ADRs was 82.7% (91/110). The percentage of subjects with renal impairment who experienced ADRs (82.7%, 91/110) was comparable to that of subjects without renal impairment who experienced ADRs (83.1%, 6,315/7,597); no new concerns were identified regarding the safety of Shingrix in individuals with renal impairment. Use in subjects with hepatic impairment was reported in 2.2% (166/7,707) and the percentage of subjects with hepatic impairment who experienced ADRs was 85.5% (142/166). The percentage of subjects with hepatic impairment who experienced ADRs (85.5%, 142/166) was comparable to that of subjects without hepatic impairment who experienced ADRs (83.1%, 6,264/7,541); no new concerns were identified regarding the safety of Shingrix in subjects with hepatic impairment. Use in individuals with immune abnormalities was reported in 9.1% (702/7,707) and the percentage of subjects with immune abnormalities who experienced ADRs was 90.6% (636/702). As a result of the multivariate logistic regression analysis, among the 7,707 subjects in the safety analysis set, the incidence proportion rate of ADRs in the subjects with and without immune abnormalities were 90.8% (513/565) and 82.0% (5,207/6,348), respectively, and “immune abnormality” did not meet the above criteria (point estimate of adjusted odds ratio, 1.331; 95% confidence interval, 0.976-1.814). Use in individuals considered to require precaution for vaccination by the investigator was reported in 0.5% (39/7,707). As the result of the univariate logistic regression analysis, the incidence proportion rates of ADRs in those classified as "Applicable" and "Not Applicable" for individuals considered to require precaution for vaccination by the investigator were 92.3% (36/39 cases) and 83.1% (6,370/7,668 cases), respectively, and did not meet the above criteria (point estimate of unadjusted odds ratio: 2.445, 95% confidence interval: 0.752-7.950).

Based on the above, no new concerns were identified in the safety of Shingrix in this investigation, and it was considered unnecessary to implement new measures to ensure proper use.

4. References

Bartels LE. 2021. Local and systemic reactogenicity of COVID-19 vaccine BNT162b2 in patients with systemic lupus erythematosus and rheumatoid arthritis. *Rheumatology International*, 41: 1925-31

Frankenthal D. 2025. Evaluation of adverse events and comorbidity exacerbation following the COVID-19 booster dose: A national survey among randomly-selected booster recipients. *PLoS ONE*, 20 (7), e0326231.

Gold MS. 2023. Anaphylaxis: Revision of the Brighton collaboration case definition. *Vaccine*, 41 (15), 2605-14

Hervé C. 2019. The how's and what's of vaccine reactogenicity. *Vaccines*, 4:39

Yousfi ME. 2005. The inflammatory response to vaccination is altered in the elderly. *Mech. Ageing Dev.* 126 (8):874-81

GlaxoSmithKline K.K.. Package insert of Shingrix for Intramuscular Injection, revised in October 2025 (Version 5).

GlaxoSmithKline K.K., Risk Management Plan for Shingrix Intramuscular Injection, submitted on February 12, 2026.

Data on file: Data submitted at the time of application (Approved on March 23, 2018, CTD2.7.4.2.1.4.3. Hypersensitivity including anaphylaxis, Page 99)

Data on file: Data submitted at the time of application (Approved on March 23, 2018, CTD2.7.4.2.1.4.2. Potential immune-mediated disease (pIMD), Page 92)

Figure 1 Subject disposition

*3: Subjects found to have been registered despite violating the registration deadline (within 8 days after the start of vaccination with Shingrix, with the date of first vaccination defined as Day 1) specified in the implementation guideline after collection of the CRF.

Table 1-1 Subject disposition

As of Sep 8, 2025

Subjects included in safety analysis

Characteristics of subjects inoculated		Subjects included in safety analysis	
		Sample size	Percentage (%)
Total		7707	100.0
Sex	Male	2495	32.4
	Female	5212	67.6
Pregnancy (females only)	No	5212	100.0
	Yes	0	0.0
Age 1 [years] Mean±SD: 66.0±10.3 Maximum: 102 Median: 66.0 Minimum: 19	<15	0	0.0
	15 ≤ to <50	91	1.2
	50 ≤ to <65	3406	44.2
	65 ≤ to <75	2524	32.7
	75 ≤	1686	21.9
Age 2 [years]	<65	3497	45.4
	65 ≤	4210	54.6
Age 3 [years]	<18	0	0.0
	18 ≤	7707	100.0
History of vaccination with herpes zoster vaccine other than Shingrix	No	7285	94.5
	Yes	115	1.5
	Unknown	307	4.0
History of herpes zoster	No	6221	80.7
	Yes	742	9.6
	Unknown	744	9.7
Eligibility as subjects requiring precaution for vaccination	No	7668	99.5
	Yes	39	0.5
Immune abnormality ^{*1}	No	7005	90.9
	Yes	702	9.1
Underlying diseases related to immune abnormalities	No	7035	91.3
	Yes	672	8.7
Prior medications (drugs that may affect immunity)	No	7072	91.8
	Yes	635	8.2
Prior therapies (therapies that may affect immunity)	No	7699	99.9
	Yes	8	0.1
Underlying disease ^{*2}	No	3761	48.8
	Yes	3946	51.2
Underlying disease (kidney disease)	No	7597	98.6
	Yes	110	1.4
Underlying disease (liver disease)	No	7541	97.8
	Yes	166	2.2
Underlying disease (other)	No	3795	49.2
	Yes	3912	50.8
Medical history	No	7073	91.8
	Yes	634	8.2
Vaccines administered for the initial vaccination other than Shingrix ^{*3}	No	7481	97.1
	Yes	226	2.9
Vaccines administered for the second vaccination other than Shingrix ^{*3} (only for subjects receiving the second vaccination)	No	7275	97.5
	Yes	189	2.5
Vaccines administered concomitantly with the initial vaccination	No	7635	99.1
	Yes	72	0.9
Vaccines administered concomitantly with the second vaccination (only for subjects receiving the second vaccination)	No	7431	99.6
	Yes	33	0.4
Medications used ^{*4}	No	4345	56.4
	Yes	3362	43.6
Therapies used other than medications ^{*5}	No	7653	99.3
	Yes	54	0.7

*1 Subjects with abnormal immune status due to underlying diseases related to immune abnormality, prior medications, or prior therapies

*2 Including underlying diseases related to immune abnormality, kidney diseases, liver diseases, and others

*3 Vaccines other than Shingrix (including concomitant vaccines) administered within 30 days from the day of vaccination with Shingrix (the day of vaccination is defined as Day 1).

*4 Drugs administered within 30 days from the day of vaccination with Shingrix (the day of vaccination is defined as Day 1)

*5 Therapies other than medications (dialysis, radiotherapy, anticoagulant therapy, surgery/others) performed within 30 days from the day of vaccination with Shingrix (the day of vaccination is defined as Day 1)

Table 1-2 Underlying diseases related to immune abnormalities: Incidence of ADRs by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)							
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Solicited adverse events		Unsolicited adverse events		Combined total	
						Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10028395	Musculoskeletal and connective tissue disorders	–	–	553	7.2	497	89.9	90	16.3	497	89.9
10028395	Musculoskeletal and connective tissue disorders	10039073	Rheumatoid arthritis	468	6.1	423	90.4	72	15.4	423	90.4
10028395	Musculoskeletal and connective tissue disorders	10040767	Sjogren's syndrome	33	0.4	30	90.9	11	33.3	30	90.9
10028395	Musculoskeletal and connective tissue disorders	10042945	Systemic Lupus Erythematosus	17	0.2	16	94.1	2	11.8	16	94.1
10028395	Musculoskeletal and connective tissue disorders	10036099	Polymyalgia rheumatica	15	0.2	12	80.0	4	26.7	12	80.0
10028395	Musculoskeletal and connective tissue disorders	10012503	Dermatomyositis	11	0.1	10	90.9	1	9.1	10	90.9
10028395	Musculoskeletal and connective tissue disorders	10037162	Psoriatic arthropathy	11	0.1	8	72.7	2	18.2	8	72.7
10028395	Musculoskeletal and connective tissue disorders	10039710	Scleroderma	11	0.1	11	100.0	3	27.3	11	100.0
10028395	Musculoskeletal and connective tissue disorders	10072736	Rheumatic disorder	10	0.1	8	80.0	1	10.0	8	80.0
10028395	Musculoskeletal and connective tissue disorders	10027754	Mixed connective tissue disease	3	0.0	3	100.0	0	0.0	3	100.0
10028395	Musculoskeletal and connective tissue disorders	10036102	Polymyositis	3	0.0	3	100.0	1	33.3	3	100.0
10028395	Musculoskeletal and connective tissue disorders	10077271	Immunoglobulin G4-related disorders	3	0.0	3	100.0	0	0.0	3	100.0
10028395	Musculoskeletal and connective tissue disorders	10078638	Systemic scleroderma	3	0.0	3	100.0	0	0.0	3	100.0
10028395	Musculoskeletal and connective tissue disorders	10062164	Seronegative arthritis	2	0.0	2	100.0	1	50.0	2	100.0
10028395	Musculoskeletal and connective tissue disorders	10009903	Collagen disorder	1	0.0	0	0.0	0	0.0	0	0.0
10028395	Musculoskeletal and connective tissue disorders	10036030	Polyarthritis	1	0.0	1	100.0	1	100.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10042061	Still's disease	1	0.0	1	100.0	1	100.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10051316	SAPHO syndrome	1	0.0	1	100.0	1	100.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10065159	Polychondritis	1	0.0	1	100.0	0	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10085753	Peripheral spondyloarthritis	1	0.0	1	100.0	1	100.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	–	–	39	0.5	35	89.7	7	17.9	35	89.7
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10035226	Plasma cell myeloma	8	0.1	8	100.0	0	0.0	8	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10006187	Breast cancer	5	0.1	5	100.0	0	0.0	5	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10000880	Acute myeloid leukaemia	4	0.1	3	75.0	2	50.0	3	75.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10009013	Chronic myeloid leukaemia	4	0.1	4	100.0	0	0.0	4	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10000846	Acute lymphocytic leukaemia	3	0.0	3	100.0	1	33.3	3	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10001413	Adult T-cell lymphoma/leukaemia	2	0.0	2	100.0	0	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10008958	Chronic lymphocytic leukaemia	2	0.0	2	100.0	1	50.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10028533	Myelodysplastic syndrome	2	0.0	2	100.0	2	100.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10017758	Gastric cancer	1	0.0	0	0.0	0	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10033609	Pancreatic carcinoma	1	0.0	0	0.0	0	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10035484	Plasmacytoma	1	0.0	1	100.0	1	100.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10050251	Castleman's disease	1	0.0	0	0.0	0	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10058467	Lung neoplasm malignant	1	0.0	0	0.0	0	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10060862	Prostate cancer	1	0.0	1	100.0	0	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10061232	Lymphoproliferative disorder	1	0.0	1	100.0	0	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10066474	Thyroid cancer	1	0.0	1	100.0	0	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10067399	Acute biphenotypic leukaemia	1	0.0	1	100.0	0	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10085128	Follicular lymphoma	1	0.0	1	100.0	0	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	–	–	22	0.3	19	86.4	3	13.6	19	86.4
10038738	Respiratory, thoracic and mediastinal disorders	10022611	Interstitial lung disease	12	0.2	10	83.3	2	16.7	10	83.3
10038738	Respiratory, thoracic and mediastinal disorders	10039085	Rhinitis allergic	5	0.1	4	80.0	1	20.0	4	80.0
10038738	Respiratory, thoracic and mediastinal disorders	10003553	Asthma	2	0.0	2	100.0	0	0.0	2	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10006458	Bronchitis chronic	1	0.0	1	100.0	0	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10014962	Eosinophilic pneumonia	1	0.0	1	100.0	0	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10029888	Obliterative bronchiolitis	1	0.0	1	100.0	0	0.0	1	100.0
10017947	Gastrointestinal disorders	–	–	13	0.2	12	92.3	1	7.7	12	92.3
10017947	Gastrointestinal disorders	10009900	Colitis ulcerative	10	0.1	10	100.0	0	0.0	10	100.0
10017947	Gastrointestinal disorders	10008882	Chronic gastritis	1	0.0	1	100.0	0	0.0	1	100.0
10017947	Gastrointestinal disorders	10010774	Constipation	1	0.0	0	0.0	0	0.0	0	0.0
10017947	Gastrointestinal disorders	10017853	Gastritis	1	0.0	1	100.0	1	100.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	–	–	13	0.2	11	84.6	4	30.8	11	84.6
10040785	Skin and subcutaneous tissue disorders	10037153	Psoriasis	5	0.1	4	80.0	2	40.0	4	80.0
10040785	Skin and subcutaneous tissue disorders	10034280	Pemphigus	2	0.0	2	100.0	1	50.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10012438	Dermatitis atopic	1	0.0	1	100.0	0	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10019617	Henoch-Schonlein purpura	1	0.0	1	100.0	0	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10020764	Hypersensitivity vasculitis	1	0.0	1	100.0	0	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10046735	Urticaria	1	0.0	1	100.0	0	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10050185	Palmoplantar pustulosis	1	0.0	1	100.0	1	100.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10081977	Senile xerosis	1	0.0	0	0.0	0	0.0	0	0.0
10005329	Blood and lymphatic system disorders	–	–	11	0.1	10	90.9	3	27.3	10	90.9
10005329	Blood and lymphatic system disorders	10083842	Immune thrombocytopenia	5	0.1	5	100.0	1	20.0	5	100.0
10005329	Blood and lymphatic system disorders	10002967	Aplastic anaemia	4	0.1	4	100.0	2	50.0	4	100.0
10005329	Blood and lymphatic system disorders	10002817	Antiphospholipid syndrome	2	0.0	1	50.0	0	0.0	1	50.0
10027433	Metabolism and nutrition disorders	–	–	11	0.1	9	81.8	0	0.0	9	81.8
10027433	Metabolism and nutrition disorders	10012601	Diabetes mellitus	7	0.1	7	100.0	0	0.0	7	100.0
10027433	Metabolism and nutrition disorders	10067585	Type 2 diabetes mellitus	2	0.0	1	50.0	0	0.0	1	50.0
10027433	Metabolism and nutrition disorders	10061273	Malnutrition	1	0.0	0	0.0	0	0.0	0	0.0
10027433	Metabolism and nutrition disorders	10067584	Type 1 diabetes mellitus	1	0.0	1	100.0	0	0.0	1	100.0

Table 1-2 Underlying diseases related to immune abnormalities: Incidence of ADRs by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)							
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Solicited adverse events		Unsolicited adverse events		Combined total	
						Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10021428	Immune system disorders	—	—	9	0.1	9	100.0	2	22.2	9	100.0
10021428	Immune system disorders	10039486	Sarcoidosis	5	0.1	5	100.0	2	40.0	5	100.0
10021428	Immune system disorders	10050894	Anti-neutrophil cytoplasmic antibody positive vasculitis	2	0.0	2	100.0	0	0.0	2	100.0
10021428	Immune system disorders	10018651	Graft versus host disease	1	0.0	1	100.0	0	0.0	1	100.0
10021428	Immune system disorders	10078117	Eosinophilic granulomatosis with polyangiitis	1	0.0	1	100.0	0	0.0	1	100.0
10047065	Vascular disorders	—	—	8	0.1	6	75.0	1	12.5	6	75.0
10047065	Vascular disorders	10020772	Hypertension	2	0.0	1	50.0	0	0.0	1	50.0
10047065	Vascular disorders	10063344	Microscopic polyangiitis	2	0.0	1	50.0	0	0.0	1	50.0
10047065	Vascular disorders	10004213	Behcet's syndrome	1	0.0	1	100.0	0	0.0	1	100.0
10047065	Vascular disorders	10018250	Giant cell arteritis	1	0.0	1	100.0	0	0.0	1	100.0
10047065	Vascular disorders	10036024	Polyarteritis nodosa	1	0.0	1	100.0	0	0.0	1	100.0
10047065	Vascular disorders	10048628	Rheumatoid vasculitis	1	0.0	1	100.0	1	100.0	1	100.0
10019805	Hepatobiliary disorders	—	—	8	0.1	5	62.5	1	12.5	5	62.5
10019805	Hepatobiliary disorders	10003827	Autoimmune hepatitis	6	0.1	4	66.7	1	16.7	4	66.7
10019805	Hepatobiliary disorders	10080429	Primary biliary cholangitis	2	0.0	1	50.0	0	0.0	1	50.0
10038359	Renal and urinary disorders	—	—	8	0.1	7	87.5	2	25.0	7	87.5
10038359	Renal and urinary disorders	10064848	Chronic kidney disease	6	0.1	5	83.3	1	16.7	5	83.3
10038359	Renal and urinary disorders	10018378	Glomerulonephritis rapidly progressive	1	0.0	1	100.0	0	0.0	1	100.0
10038359	Renal and urinary disorders	10021263	IgA nephropathy	1	0.0	1	100.0	1	100.0	1	100.0
10038359	Renal and urinary disorders	10038435	Renal failure	1	0.0	1	100.0	0	0.0	1	100.0
10042613	Surgical and medical procedures	—	—	8	0.1	8	100.0	3	37.5	8	100.0
10042613	Surgical and medical procedures	10038533	Renal transplant	7	0.1	7	100.0	3	42.9	7	100.0
10042613	Surgical and medical procedures	10041642	Splenectomy	1	0.0	1	100.0	0	0.0	1	100.0
10014698	Endocrine disorders	—	—	7	0.1	6	85.7	3	42.9	6	85.7
10014698	Endocrine disorders	10049046	Autoimmune thyroiditis	3	0.0	2	66.7	1	33.3	2	66.7
10014698	Endocrine disorders	10021114	Hypothyroidism	2	0.0	2	100.0	1	50.0	2	100.0
10014698	Endocrine disorders	10018706	Graves' disease	1	0.0	1	100.0	1	100.0	1	100.0
10014698	Endocrine disorders	10021067	Hypopituitarism	1	0.0	1	100.0	0	0.0	1	100.0
10029205	Nervous system disorders	—	—	6	0.1	5	83.3	0	0.0	5	83.3
10029205	Nervous system disorders	10008034	Cerebellar infarction	1	0.0	0	0.0	0	0.0	0	0.0
10029205	Nervous system disorders	10027599	Migraine	1	0.0	1	100.0	0	0.0	1	100.0
10029205	Nervous system disorders	10028417	Myasthenia gravis	1	0.0	1	100.0	0	0.0	1	100.0
10029205	Nervous system disorders	10036376	Post herpetic neuralgia	1	0.0	1	100.0	0	0.0	1	100.0
10029205	Nervous system disorders	10042272	Subacute combined cord degeneration	1	0.0	1	100.0	0	0.0	1	100.0
10029205	Nervous system disorders	10077875	Neuromyelitis optica spectrum disorder	1	0.0	1	100.0	0	0.0	1	100.0
10021881	Infections and infestations	—	—	3	0.0	3	100.0	1	33.3	3	100.0
10021881	Infections and infestations	10000565	Acquired immunodeficiency syndrome	1	0.0	1	100.0	0	0.0	1	100.0
10021881	Infections and infestations	10044696	Tropical spastic paresis	1	0.0	1	100.0	0	0.0	1	100.0
10021881	Infections and infestations	10061663	Atypical mycobacterial infection	1	0.0	1	100.0	1	100.0	1	100.0
10037175	Psychiatric disorders	—	—	1	0.0	1	100.0	0	0.0	1	100.0
10037175	Psychiatric disorders	10022437	Insomnia	1	0.0	1	100.0	0	0.0	1	100.0
10007541	Cardiac disorders	—	—	1	0.0	1	100.0	0	0.0	1	100.0
10007541	Cardiac disorders	10003119	Arrhythmia	1	0.0	1	100.0	0	0.0	1	100.0
10010331	Congenital, familial and genetic disorders	—	—	1	0.0	0	0.0	0	0.0	0	0.0
10010331	Congenital, familial and genetic disorders	10090911	Hereditary breast and ovarian cancer syndrome	1	0.0	0	0.0	0	0.0	0	0.0
10018065	General disorders and administration site conditions	—	—	1	0.0	1	100.0	1	100.0	1	100.0
10018065	General disorders and administration site conditions	10018691	Granuloma	1	0.0	1	100.0	1	100.0	1	100.0

(Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

MedDRA/J (28.0)

Table 1-3 Prior medications (drugs that may affect immunity): Incidence of ADRs by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)							
			Number of subjects treated	Percentage of subjects treated (%)	Solicited adverse events		Unsolicited adverse events		Combined total	
					Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
399	Other agents affecting metabolism-Miscellaneous	—	482	6.3	442	91.7	76	15.8	442	91.7
3999016	Other agents affecting metabolism-Miscellaneous	Methotrexate	287	3.7	271	94.4	46	16.0	271	94.4
3999031	Other agents affecting metabolism-Miscellaneous	Iguratimod	80	1.0	73	91.3	12	15.0	73	91.3
3999014	Other agents affecting metabolism-Miscellaneous	Tacrolimus Hydrate	58	0.8	57	98.3	13	22.4	57	98.3
3999048	Other agents affecting metabolism-Miscellaneous	Upadacitinib Hydrate	39	0.5	35	89.7	7	17.9	35	89.7
3999433	Other agents affecting metabolism-Miscellaneous	Golimumab (Genetical Recombination)	36	0.5	33	91.7	8	22.2	33	91.7
3999043	Other agents affecting metabolism-Miscellaneous	Baricitinib	35	0.5	33	94.3	3	8.6	33	94.3
3999429	Other agents affecting metabolism-Miscellaneous	Abatacept (Genetical Recombination)	25	0.3	24	96.0	6	24.0	24	96.0
3999424	Other agents affecting metabolism-Miscellaneous	Etanercept (Genetical Recombination)	24	0.3	24	100.0	6	25.0	24	100.0
3999426	Other agents affecting metabolism-Miscellaneous	Adalimumab (Genetical Recombination)	24	0.3	19	79.2	4	16.7	19	79.2
3999444	Other agents affecting metabolism-Miscellaneous	Sarilumab (Genetical Recombination)	20	0.3	15	75.0	0	0.0	15	75.0
3999002	Other agents affecting metabolism-Miscellaneous	Mizoribine	18	0.2	16	88.9	1	5.6	16	88.9
3999053	Other agents affecting metabolism-Miscellaneous	Filgotinib Maleate	17	0.2	14	82.4	0	0.0	14	82.4
3999034	Other agents affecting metabolism-Miscellaneous	Tofacitinib Citrate	13	0.2	12	92.3	3	23.1	12	92.3
3999017	Other agents affecting metabolism-Miscellaneous	Mycophenolate Mofetil	9	0.1	9	100.0	4	44.4	9	100.0
3999004	Other agents affecting metabolism-Miscellaneous	Ciclosporin	8	0.1	8	100.0	2	25.0	8	100.0
3999437	Other agents affecting metabolism-Miscellaneous	Certolizumab Pegol (Genetical Recombination)	8	0.1	7	87.5	0	0.0	7	87.5
3999020	Other agents affecting metabolism-Miscellaneous	Leflunomide	6	0.1	4	66.7	2	33.3	4	66.7
3999046	Other agents affecting metabolism-Miscellaneous	Peficitinib Hydrobromide	6	0.1	6	100.0	2	33.3	6	100.0
3999022	Other agents affecting metabolism-Miscellaneous	Everolimus	4	0.1	4	100.0	3	75.0	4	100.0
3999038	Other agents affecting metabolism-Miscellaneous	Hydroxychloroquine Sulfate	4	0.1	4	100.0	0	0.0	4	100.0
3999005	Other agents affecting metabolism-Miscellaneous	Azathioprine	3	0.0	3	100.0	0	0.0	3	100.0
3999042	Other agents affecting metabolism-Miscellaneous	Apremilast	2	0.0	2	100.0	1	50.0	2	100.0
3999442	Other agents affecting metabolism-Miscellaneous	Ixekizumab (Genetical Recombination)	2	0.0	1	50.0	0	0.0	1	50.0
3999445	Other agents affecting metabolism-Miscellaneous	Belimumab (Genetical Recombination)	2	0.0	2	100.0	1	50.0	2	100.0
3999457	Other agents affecting metabolism-Miscellaneous	Adalimumab (Genetical Recombination) [Biosimilar 1]	2	0.0	2	100.0	2	100.0	2	100.0
3999467	Other agents affecting metabolism-Miscellaneous	Ozoralizumab (Genetical Recombination)	2	0.0	0	0.0	0	0.0	0	0.0
3999468	Other agents affecting metabolism-Miscellaneous	Methotrexate	2	0.0	1	50.0	0	0.0	1	50.0
3999018	Other agents affecting metabolism-Miscellaneous	Alendronate Sodium Hydrate	1	0.0	1	100.0	0	0.0	1	100.0
3999039	Other agents affecting metabolism-Miscellaneous	Nintedanib Ethanesulfonate	1	0.0	1	100.0	0	0.0	1	100.0
3999439	Other agents affecting metabolism-Miscellaneous	Secukinumab (Genetical Recombination)	1	0.0	1	100.0	0	0.0	1	100.0
3999441	Other agents affecting metabolism-Miscellaneous	Brodalumab (Genetical Recombination)	1	0.0	1	100.0	0	0.0	1	100.0
3999448	Other agents affecting metabolism-Miscellaneous	Etanercept (Genetical Recombination) [Biosimilar 1]	1	0.0	0	0.0	0	0.0	0	0.0
245	Adrenal hormone preparations	—	202	2.6	184	91.1	33	16.3	184	91.1
2456002	Adrenal hormone preparations	Prednisolone	178	2.3	162	91.0	29	16.3	162	91.0
2456003	Adrenal hormone preparations	Methylprednisolone	15	0.2	14	93.3	4	26.7	14	93.3
2454002	Adrenal hormone preparations	Dexamethasone	5	0.1	5	100.0	0	0.0	5	100.0
2454407	Adrenal hormone preparations	Dexamethasone Palmitate	4	0.1	4	100.0	0	0.0	4	100.0
2452002	Adrenal hormone preparations	Hydrocortisone	1	0.0	1	100.0	0	0.0	1	100.0
2454004	Adrenal hormone preparations	Betamethasone	1	0.0	1	100.0	0	0.0	1	100.0
2459100	Adrenal hormone preparations	Betamethasone/d-Chlorpheniramine Maleate	1	0.0	0	0.0	0	0.0	0	0.0

Table 1-3 Prior medications (drugs that may affect immunity): Incidence of ADRs by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)							
			Number of subjects treated	Percentage of subjects treated (%)	Solicited adverse events		Unsolicited adverse events		Combined total	
					Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
621	Sulfonamides	—	73	0.9	68	93.2	12	16.4	68	93.2
6219001	Sulfonamides	Salazosulfapyridine	73	0.9	68	93.2	12	16.4	68	93.2
639	Biological preparations-Miscellaneous	—	38	0.5	34	89.5	11	28.9	34	89.5
6399421	Biological preparations-Miscellaneous	Tocilizumab (Genetical Recombination)	38	0.5	34	89.5	11	28.9	34	89.5
442	Stimulation therapy agents	—	27	0.4	25	92.6	2	7.4	25	92.6
4420002	Stimulation therapy agents	Bucillamine	22	0.3	20	90.9	1	4.5	20	90.9
4420001	Stimulation therapy agents	Auranofin	3	0.0	3	100.0	0	0.0	3	100.0
4420402	Stimulation therapy agents	Sodium Aurothiomalate	3	0.0	2	66.7	1	33.3	2	66.7
239	Digestive organ agents-Miscellaneous	—	18	0.2	14	77.8	1	5.6	14	77.8
2399499	Digestive organ agents-Miscellaneous	Infliximab (Genetical Recombination)	13	0.2	9	69.2	1	7.7	9	69.2
2399009	Digestive organ agents-Miscellaneous	Mesalazine	4	0.1	4	100.0	0	0.0	4	100.0
2399716	Digestive organ agents-Miscellaneous	Budesonide	1	0.0	1	100.0	0	0.0	1	100.0
429	Antineoplastics-Miscellaneous	—	15	0.2	14	93.3	3	20.0	14	93.3
4291010	Antineoplastics-Miscellaneous	Anastrozole	3	0.0	2	66.7	0	0.0	2	66.7
4291049	Antineoplastics-Miscellaneous	Exazomib Citrate	2	0.0	2	100.0	0	0.0	2	100.0
4291454	Antineoplastics-Miscellaneous	Isatuximab (Genetical Recombination)	2	0.0	2	100.0	0	0.0	2	100.0
4291011	Antineoplastics-Miscellaneous	Imatinib Mesilate	1	0.0	1	100.0	1	100.0	1	100.0
4291015	Antineoplastics-Miscellaneous	Letrozole	1	0.0	1	100.0	0	0.0	1	100.0
4291020	Antineoplastics-Miscellaneous	Dasatinib Hydrate	1	0.0	1	100.0	0	0.0	1	100.0
4291024	Antineoplastics-Miscellaneous	Lenalidomide Hydrate	1	0.0	1	100.0	0	0.0	1	100.0
4291034	Antineoplastics-Miscellaneous	Ruxolitinib Phosphate	1	0.0	1	100.0	1	100.0	1	100.0
4291039	Antineoplastics-Miscellaneous	Lenvatinib Mesilate	1	0.0	1	100.0	0	0.0	1	100.0
4291043	Antineoplastics-Miscellaneous	Ibrutinib	1	0.0	1	100.0	1	100.0	1	100.0
4291500	Antineoplastics-Miscellaneous	Daratumumab (Genetical Recombination)/Vorhyaluronidase Alfa (Genetical Recombination)	1	0.0	1	100.0	0	0.0	1	100.0
313	Vitamin B preparations (except Vitamin B1)	—	7	0.1	7	100.0	2	28.6	7	100.0
3135002	Vitamin B preparations (except Vitamin B1)	Folic acid	7	0.1	7	100.0	2	28.6	7	100.0
449	Allergic agents-Miscellaneous	—	7	0.1	6	85.7	1	14.3	6	85.7
4490023	Allergic agents-Miscellaneous	Fexofenadine Hydrochloride	2	0.0	2	100.0	0	0.0	2	100.0
4490028	Allergic agents-Miscellaneous	Levocetirizine Hydrochloride	2	0.0	2	100.0	0	0.0	2	100.0
4490035	Allergic agents-Miscellaneous	Japanese cedar pollen extract	2	0.0	1	50.0	1	50.0	1	50.0
4490033	Allergic agents-Miscellaneous	Bilastine	1	0.0	1	100.0	0	0.0	1	100.0
114	Antipyretics, analgesics, and anti-inflammatory agents	—	5	0.1	4	80.0	0	0.0	4	80.0
1149031	Antipyretics, analgesics, and anti-inflammatory agents	Actarit	2	0.0	1	50.0	0	0.0	1	50.0
1141007	Antipyretics, analgesics, and anti-inflammatory agents	Acetaminophen	1	0.0	1	100.0	0	0.0	1	100.0
1149023	Antipyretics, analgesics, and anti-inflammatory agents	Extract from inflamed cutaneous tissue of rabbits inoculated with vaccinia virus	1	0.0	1	100.0	0	0.0	1	100.0
1149032	Antipyretics, analgesics, and anti-inflammatory agents	Etodolac	1	0.0	1	100.0	0	0.0	1	100.0
1149037	Antipyretics, analgesics, and anti-inflammatory agents	Celecoxib	1	0.0	1	100.0	0	0.0	1	100.0
1149038	Antipyretics, analgesics, and anti-inflammatory agents	Tramadol Hydrochloride	1	0.0	1	100.0	0	0.0	1	100.0
243	Thyroid and parathyroid hormone preparations	—	4	0.1	4	100.0	1	25.0	4	100.0
2431004	Thyroid and parathyroid hormone preparations	Levothyroxine Sodium Hydrate	3	0.0	3	100.0	0	0.0	3	100.0
2432001	Thyroid and parathyroid hormone preparations	Thiamazole	1	0.0	1	100.0	1	100.0	1	100.0

Table 1-3 Prior medications (drugs that may affect immunity): Incidence of ADRs by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)							
			Number of subjects treated	Percentage of subjects treated (%)	Solicited adverse events		Unsolicited adverse events		Combined total	
					Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
218	Hyperlipidemia agents	—	2	0.0	2	100.0	1	50.0	2	100.0
2189010	Hyperlipidemia agents	Pravastatin Sodium	1	0.0	1	100.0	0	0.0	1	100.0
2189015	Hyperlipidemia agents	Atorvastatin Calcium Hydrate	1	0.0	1	100.0	1	100.0	1	100.0
264	Analgesics, anti-itchings, astringents, anti-inflammatory agents	—	2	0.0	2	100.0	0	0.0	2	100.0
2646730	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Betamethasone Butyrate Propionate	1	0.0	1	100.0	0	0.0	1	100.0
2647709	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Betamethasone Valerate/Gentamicin Sulfate	1	0.0	1	100.0	0	0.0	1	100.0
2649729	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Ketoprofen	1	0.0	1	100.0	0	0.0	1	100.0
62	Chemotherapeutics	—	1	0.0	0	0.0	0	0.0	0	0.0
62	Chemotherapeutics	Chemotherapeutics	1	0.0	0	0.0	0	0.0	0	0.0
113	Antiepileptics	—	1	0.0	1	100.0	0	0.0	1	100.0
1132002	Antiepileptics	Phenytoin	1	0.0	1	100.0	0	0.0	1	100.0
1139010	Antiepileptics	Levetiracetam	1	0.0	1	100.0	0	0.0	1	100.0
119	Agents affecting central nervous system-Miscellaneous	—	1	0.0	1	100.0	0	0.0	1	100.0
1190017	Agents affecting central nervous system-Miscellaneous	Pregabalin	1	0.0	1	100.0	0	0.0	1	100.0
131	Ophthalmic agents	—	1	0.0	1	100.0	0	0.0	1	100.0
1319720	Ophthalmic agents	Purified sodium hyaluronate	1	0.0	1	100.0	0	0.0	1	100.0
1319808	Ophthalmic agents	Boric acid-inorganic salts combination	1	0.0	1	100.0	0	0.0	1	100.0
132	Otic and nasal agents	—	1	0.0	1	100.0	0	0.0	1	100.0
1329707	Otic and nasal agents	Fluticasone Propionate	1	0.0	1	100.0	0	0.0	1	100.0
214	Antihypertensives	—	1	0.0	1	100.0	0	0.0	1	100.0
2149040	Antihypertensives	Candesartan Cilexetil	1	0.0	1	100.0	0	0.0	1	100.0
217	Vasodilators	—	1	0.0	1	100.0	0	0.0	1	100.0
2171008	Vasodilators	Verapamil Hydrochloride	1	0.0	1	100.0	0	0.0	1	100.0
229	Respiratory organ agents-Miscellaneous	—	1	0.0	1	100.0	0	0.0	1	100.0
2290402	Respiratory organ agents-Miscellaneous	Benralizumab (Genetical Recombination)	1	0.0	1	100.0	0	0.0	1	100.0
232	Peptic ulcer agents	—	1	0.0	1	100.0	1	100.0	1	100.0
2329021	Peptic ulcer agents	Rebamipide	1	0.0	1	100.0	1	100.0	1	100.0
311	Vitamins A and D preparations	—	1	0.0	1	100.0	0	0.0	1	100.0
3112006	Vitamins A and D preparations	Eldecalcitol	1	0.0	1	100.0	0	0.0	1	100.0
339	Blood and body fluid agents-Miscellaneous	—	1	0.0	1	100.0	0	0.0	1	100.0
3399003	Blood and body fluid agents-Miscellaneous	Limaprost Alfadex	1	0.0	1	100.0	0	0.0	1	100.0
394	Gout preparations	—	1	0.0	1	100.0	0	0.0	1	100.0
3941001	Gout preparations	Colchicine	1	0.0	1	100.0	0	0.0	1	100.0
421	Alkylating agents	—	1	0.0	1	100.0	0	0.0	1	100.0
4211002	Alkylating agents	Cyclophosphamide Hydrate	1	0.0	1	100.0	0	0.0	1	100.0
422	Antimetabolites	—	1	0.0	1	100.0	0	0.0	1	100.0
4229001	Antimetabolites	Hydroxycarbamide	1	0.0	1	100.0	0	0.0	1	100.0
520	Traditional Chinese medicines	—	1	0.0	1	100.0	1	100.0	1	100.0
5200131	Traditional Chinese medicines	Hochuekkito	1	0.0	1	100.0	1	100.0	1	100.0

Table 1-3 Prior medications (drugs that may affect immunity): Incidence of ADRs by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)							
			Number of subjects treated	Percentage of subjects treated (%)	Solicited adverse events		Unsolicited adverse events		Combined total	
					Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
614	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	—	1	0.0	1	100.0	0	0.0	1	100.0
6149003	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	Clarithromycin	1	0.0	1	100.0	0	0.0	1	100.0
625	Antivirals	—	1	0.0	1	100.0	0	0.0	1	100.0
6250029	Antivirals	Entecavir Hydrate	1	0.0	1	100.0	0	0.0	1	100.0
999	Therapeutic effect unknown	—	1	0.0	1	100.0	0	0.0	1	100.0
GSK95015401	Therapeutic effect unknown	Unknown	1	0.0	1	100.0	0	0.0	1	100.0

(Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Table 1-4 Prior therapies

As of Sep 8, 2025

Subjects included in safety analysis

Item/Category		Subjects included in safety analysis (n = 7707)			
		Sample size	Percentage of subjects treated (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
Prior therapies (therapies that may affect immunity)	Dialysis	5	0.1	4	80.0
	Radiotherapy	1	0.0	1	100.0
	Anticoagulant therapy	0	0.0	0	–
	Surgery/Other	2	0.0	1	50.0
	Allogeneic hematopoietic stem cell transplantation	1	0.0	1	100.0
	Breast cancer surgery	1	0.0	0	0.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10027433	Metabolism and nutrition disorders	--	--	1801	23.4	1575	87.5
10027433	Metabolism and nutrition disorders	10058108	Dyslipidaemia	691	9.0	617	89.3
10027433	Metabolism and nutrition disorders	10062060	Hyperlipidaemia	484	6.3	406	83.9
10027433	Metabolism and nutrition disorders	10012601	Diabetes mellitus	378	4.9	322	85.2
10027433	Metabolism and nutrition disorders	10020603	Hypercholesterolaemia	255	3.3	231	90.6
10027433	Metabolism and nutrition disorders	10020903	Hyperuricaemia	202	2.6	178	88.1
10027433	Metabolism and nutrition disorders	10067585	Type 2 diabetes mellitus	162	2.1	136	84.0
10027433	Metabolism and nutrition disorders	10018627	Gout	23	0.3	16	69.6
10027433	Metabolism and nutrition disorders	10061227	Lipid metabolism disorder	13	0.2	11	84.6
10027433	Metabolism and nutrition disorders	10016880	Folate deficiency	10	0.1	10	100.0
10027433	Metabolism and nutrition disorders	10047626	Vitamin D deficiency	10	0.1	10	100.0
10027433	Metabolism and nutrition disorders	10029883	Obesity	8	0.1	7	87.5
10027433	Metabolism and nutrition disorders	10067584	Type 1 diabetes mellitus	8	0.1	8	100.0
10027433	Metabolism and nutrition disorders	10018429	Glucose tolerance impaired	7	0.1	7	100.0
10027433	Metabolism and nutrition disorders	10020646	Hypokalaemia	7	0.1	6	85.7
10027433	Metabolism and nutrition disorders	10048259	Zinc deficiency	7	0.1	5	71.4
10027433	Metabolism and nutrition disorders	10021015	Hypokalaemia	6	0.1	5	83.3
10027433	Metabolism and nutrition disorders	10021135	Hypovitaminosis	6	0.1	6	100.0
10027433	Metabolism and nutrition disorders	10020947	Hypocalcaemia	5	0.1	4	80.0
10027433	Metabolism and nutrition disorders	10047601	Vitamin B1 deficiency	4	0.1	4	100.0
10027433	Metabolism and nutrition disorders	10058097	Metabolic disorder	4	0.1	2	50.0
10027433	Metabolism and nutrition disorders	10047623	Vitamin C deficiency	3	0.0	2	66.7
10027433	Metabolism and nutrition disorders	10061428	Decreased appetite	3	0.0	3	100.0
10027433	Metabolism and nutrition disorders	10020942	Hypoalbuminaemia	2	0.0	1	50.0
10027433	Metabolism and nutrition disorders	10062770	Hyperamylasaemia	2	0.0	2	100.0
10027433	Metabolism and nutrition disorders	10020583	Hypercalcaemia	1	0.0	1	100.0
10027433	Metabolism and nutrition disorders	10020711	Hyperphosphataemia	1	0.0	1	100.0
10027433	Metabolism and nutrition disorders	10021148	Hypozinaemia	1	0.0	1	100.0
10027433	Metabolism and nutrition disorders	10033660	Pancreatogenous diabetes	1	0.0	1	100.0
10027433	Metabolism and nutrition disorders	10047609	Vitamin B12 deficiency	1	0.0	1	100.0
10027433	Metabolism and nutrition disorders	10047631	Vitamin E deficiency	1	0.0	1	100.0
10027433	Metabolism and nutrition disorders	10060851	Hyperphosphatasaemia	1	0.0	1	100.0
10027433	Metabolism and nutrition disorders	10061273	Malnutrition	1	0.0	0	0.0
10047065	Vascular disorders	--	--	1768	22.9	1522	86.1
10047065	Vascular disorders	10020772	Hypertension	1710	22.2	1468	85.8
10047065	Vascular disorders	10062585	Peripheral arterial occlusive disease	24	0.3	21	87.5
10047065	Vascular disorders	10015488	Essential hypertension	17	0.2	16	94.1
10047065	Vascular disorders	10034636	Peripheral vascular disorder	8	0.1	5	62.5
10047065	Vascular disorders	10051055	Deep vein thrombosis	8	0.1	8	100.0
10047065	Vascular disorders	10002882	Aortic aneurysm	4	0.1	3	75.0
10047065	Vascular disorders	10062599	Arterial occlusive disease	4	0.1	4	100.0
10047065	Vascular disorders	10002895	Aortic dissection	3	0.0	3	100.0
10047065	Vascular disorders	10003210	Arteriosclerosis	2	0.0	2	100.0
10047065	Vascular disorders	10025282	Lymphoedema	2	0.0	2	100.0
10047065	Vascular disorders	10037912	Raynaud's phenomenon	2	0.0	2	100.0
10047065	Vascular disorders	10043570	Thrombophlebitis	2	0.0	2	100.0
10047065	Vascular disorders	10048628	Rheumatoid vasculitis	2	0.0	1	50.0
10047065	Vascular disorders	10063344	Microscopic polyangiitis	2	0.0	1	50.0
10047065	Vascular disorders	10004213	Behcet's syndrome	1	0.0	1	100.0
10047065	Vascular disorders	10014522	Embolism venous	1	0.0	1	100.0
10047065	Vascular disorders	10018250	Giant cell arteritis	1	0.0	1	100.0
10047065	Vascular disorders	10021097	Hypotension	1	0.0	1	100.0
10047065	Vascular disorders	10031127	Orthostatic hypotension	1	0.0	1	100.0
10047065	Vascular disorders	10034567	Peripheral circulatory failure	1	0.0	1	100.0
10047065	Vascular disorders	10036024	Polyarteritis nodosa	1	0.0	1	100.0
10047065	Vascular disorders	10043097	Takayasu's arteritis	1	0.0	1	100.0
10047065	Vascular disorders	10043540	Thromboangiitis obliterans	1	0.0	1	100.0
10047065	Vascular disorders	10043607	Thrombosis	1	0.0	1	100.0
10047065	Vascular disorders	10047249	Venous thrombosis	1	0.0	1	100.0
10047065	Vascular disorders	10055798	Haemorrhage	1	0.0	1	100.0
10047065	Vascular disorders	10057453	Aortic dilatation	1	0.0	1	100.0
10047065	Vascular disorders	10057521	Peripheral artery aneurysm	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	--	--	1200	15.6	1078	89.8
10028395	Musculoskeletal and connective tissue disorders	10039073	Rheumatoid arthritis	530	6.9	479	90.4
10028395	Musculoskeletal and connective tissue disorders	10031282	Osteoporosis	526	6.8	476	90.5
10028395	Musculoskeletal and connective tissue disorders	10031161	Osteoarthritis	96	1.2	80	83.3
10028395	Musculoskeletal and connective tissue disorders	10030988	Back pain	87	1.1	81	93.1
10028395	Musculoskeletal and connective tissue disorders	10025005	Lumbar spinal stenosis	66	0.9	57	86.4
10028395	Musculoskeletal and connective tissue disorders	10040767	Sjogren's syndrome	42	0.5	39	92.9
10028395	Musculoskeletal and connective tissue disorders	10041591	Spinal osteoarthritis	35	0.5	32	91.4
10028395	Musculoskeletal and connective tissue disorders	10028334	Muscle spasms	29	0.4	25	86.2
10028395	Musculoskeletal and connective tissue disorders	10034464	Periarthritis	27	0.4	25	92.6
10028395	Musculoskeletal and connective tissue disorders	10036099	Polymyalgia rheumatica	19	0.2	16	84.2
10028395	Musculoskeletal and connective tissue disorders	10042945	Systemic Lupus Erythematosus	19	0.2	18	94.7
10028395	Musculoskeletal and connective tissue disorders	10082214	Spinal stenosis	19	0.2	15	78.9
10028395	Musculoskeletal and connective tissue disorders	10050296	Intervertebral disc protrusion	17	0.2	17	100.0
10028395	Musculoskeletal and connective tissue disorders	10012503	Dermatomyositis	15	0.2	14	93.3
10028395	Musculoskeletal and connective tissue disorders	10039710	Scleroderma	15	0.2	15	100.0
10028395	Musculoskeletal and connective tissue disorders	10052904	Musculoskeletal stiffness	15	0.2	14	93.3
10028395	Musculoskeletal and connective tissue disorders	10072736	Rheumatic disorder	14	0.2	12	85.7
10028395	Musculoskeletal and connective tissue disorders	10037162	Psoriatic arthropathy	13	0.2	9	69.2
10028395	Musculoskeletal and connective tissue disorders	10048439	Fibromyalgia	13	0.2	11	84.6
10028395	Musculoskeletal and connective tissue disorders	10003239	Anthraxia	12	0.2	11	91.7
10028395	Musculoskeletal and connective tissue disorders	10063550	Spondylolisthesis	10	0.1	9	90.0
10028395	Musculoskeletal and connective tissue disorders	10028411	Myalgia	7	0.1	7	100.0
10028395	Musculoskeletal and connective tissue disorders	10003246	Arthritis	6	0.1	5	83.3
10028395	Musculoskeletal and connective tissue disorders	10036102	Polymyositis	6	0.1	6	100.0
10028395	Musculoskeletal and connective tissue disorders	10031285	Osteoporosis postmenopausal	5	0.1	5	100.0
10028395	Musculoskeletal and connective tissue disorders	10077271	Immunoglobulin G4-related disorders	5	0.1	5	100.0
10028395	Musculoskeletal and connective tissue disorders	10078638	Systemic scleroderma	5	0.1	5	100.0
10028395	Musculoskeletal and connective tissue disorders	10036030	Polyarthritis	4	0.1	4	100.0
10028395	Musculoskeletal and connective tissue disorders	10027754	Mixed connective tissue disease	3	0.0	3	100.0
10028395	Musculoskeletal and connective tissue disorders	10048780	Myofascial pain syndrome	3	0.0	3	100.0
10028395	Musculoskeletal and connective tissue disorders	10061521	Intervertebral disc disorder	3	0.0	3	100.0
10028395	Musculoskeletal and connective tissue disorders	10083338	Atlantoaxial subluxation	3	0.0	2	66.7
10028395	Musculoskeletal and connective tissue disorders	10028836	Neck pain	2	0.0	2	100.0
10028395	Musculoskeletal and connective tissue disorders	10035155	Plantar fasciitis	2	0.0	2	100.0
10028395	Musculoskeletal and connective tissue disorders	10043261	Tenosynovitis	2	0.0	1	50.0
10028395	Musculoskeletal and connective tissue disorders	10044654	Trigger finger	2	0.0	1	50.0
10028395	Musculoskeletal and connective tissue disorders	10061371	Spondylitis	2	0.0	1	50.0
10028395	Musculoskeletal and connective tissue disorders	10062164	Seronegative arthritis	2	0.0	2	100.0
10028395	Musculoskeletal and connective tissue disorders	10009903	Collagen disorder	1	0.0	0	0.0
10028395	Musculoskeletal and connective tissue disorders	10024829	Loose body in joint	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10027982	Morphoea	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10033425	Pain in extremity	1	0.0	1	100.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10028395	Musculoskeletal and connective tissue disorders	10039722	Scoliosis	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10042061	Still's disease	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10042858	Synovial cyst	1	0.0	0	0.0
10028395	Musculoskeletal and connective tissue disorders	10042868	Synovitis	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10048592	Musculoskeletal disorder	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10048710	Sacral pain	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10051316	SAPHO syndrome	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10056698	Tenosynovitis stenosis	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10058660	Spinal ligament ossification	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10061209	Hip deformity	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10061246	Intervertebral disc degeneration	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10062061	Knee deformity	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10062575	Muscle contracture	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10065159	Polychondritis	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10066267	Paraneoplastic dermatomyositis	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10081810	Psustolitic arthro-ostitis	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10085753	Peripheral spondyloarthritis	1	0.0	1	100.0
10028395	Musculoskeletal and connective tissue disorders	10086355	Rotator cuff tear arthropathy	1	0.0	1	100.0
10017947	Gastrointestinal disorders			774	10.0	692	89.4
10017947	Gastrointestinal disorders	10017885	Gastroesophageal reflux disease	373	4.8	321	86.1
10017947	Gastrointestinal disorders	10010774	Constipation	220	2.9	201	91.4
10017947	Gastrointestinal disorders	10008882	Chronic gastritis	165	2.1	154	93.3
10017947	Gastrointestinal disorders	10017822	Gastric ulcer	75	1.0	72	96.0
10017947	Gastrointestinal disorders	10017853	Gastritis	59	0.8	54	91.5
10017947	Gastrointestinal disorders	10023003	Irritable bowel syndrome	24	0.3	20	83.3
10017947	Gastrointestinal disorders	10009900	Colitis ulcerative	17	0.2	16	94.1
10017947	Gastrointestinal disorders	10013946	Dyspepsia	14	0.2	14	100.0
10017947	Gastrointestinal disorders	10012735	Diarrhoea	12	0.2	7	58.3
10017947	Gastrointestinal disorders	10014893	Enterocolitis	9	0.1	9	100.0
10017947	Gastrointestinal disorders	10019022	Haemorrhoids	8	0.1	7	87.5
10017947	Gastrointestinal disorders	10000060	Abdominal distension	6	0.1	6	100.0
10017947	Gastrointestinal disorders	10082129	Dysbiosis	6	0.1	6	100.0
10017947	Gastrointestinal disorders	10042128	Stomatitis	5	0.1	5	100.0
10017947	Gastrointestinal disorders	10013559	Diverticulum intestinal	4	0.1	3	75.0
10017947	Gastrointestinal disorders	10017817	Gastric polyps	4	0.1	4	100.0
10017947	Gastrointestinal disorders	10017865	Gastritis erosive	4	0.1	4	100.0
10017947	Gastrointestinal disorders	10028813	Nausea	4	0.1	4	100.0
10017947	Gastrointestinal disorders	10033649	Pancreatitis chronic	4	0.1	4	100.0
10017947	Gastrointestinal disorders	10051589	Large intestine polyp	4	0.1	3	75.0
10017947	Gastrointestinal disorders	10008399	Change of bowel habit	3	0.0	3	100.0
10017947	Gastrointestinal disorders	10013836	Duodenal ulcer	3	0.0	3	100.0
10017947	Gastrointestinal disorders	10020028	Hiatus hernia	3	0.0	3	100.0
10017947	Gastrointestinal disorders	10044055	Toothache	3	0.0	3	100.0
10017947	Gastrointestinal disorders	10012318	Dental caries	2	0.0	2	100.0
10017947	Gastrointestinal disorders	10024396	Leukoplakia oral	2	0.0	2	100.0
10017947	Gastrointestinal disorders	10033615	Pancreatic cyst	2	0.0	2	100.0
10017947	Gastrointestinal disorders	10047700	Vomiting	2	0.0	2	100.0
10017947	Gastrointestinal disorders	10000059	Abdominal discomfort	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10000081	Abdominal pain	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10000087	Abdominal pain upper	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10002509	Angular cheilitis	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10011401	Crohn's disease	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10013781	Dry mouth	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10013810	Dumping syndrome	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10017902	Gastroenteritis eosinophilic	1	0.0	0	0.0
10017947	Gastrointestinal disorders	10017944	Gastroenteritis disorders	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10021309	Ileal ulcer	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10034650	Peritoneal adhesions	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10049082	Pancreatic mass	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10049305	Gingival oedema	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10051252	Pancreatolithiasis	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10060709	Gastrointestinal erosion	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10061820	Diverticular perforation	1	0.0	1	100.0
10017947	Gastrointestinal disorders	10071275	Functional gastrointestinal disorder	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders			611	7.9	553	90.5
10038738	Respiratory, thoracic and mediastinal disorders	10039085	Rhinitis allergic	291	3.8	270	92.8
10038738	Respiratory, thoracic and mediastinal disorders	10003553	Asthma	221	2.9	202	91.4
10038738	Respiratory, thoracic and mediastinal disorders	10022611	Interstitial lung disease	47	0.6	41	87.2
10038738	Respiratory, thoracic and mediastinal disorders	10040979	Sleep apnoea syndrome	46	0.6	41	89.1
10038738	Respiratory, thoracic and mediastinal disorders	10006458	Bronchitis chronic	40	0.5	35	87.5
10038738	Respiratory, thoracic and mediastinal disorders	10009023	Chronic obstructive pulmonary disease	33	0.4	29	87.9
10038738	Respiratory, thoracic and mediastinal disorders	10035618	Pleurisy	6	0.1	5	83.3
10038738	Respiratory, thoracic and mediastinal disorders	10006445	Bronchiectasis	5	0.1	5	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10037400	Pulmonary hypertension	5	0.1	5	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10014561	Emphysema	4	0.1	4	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10037377	Pulmonary embolism	3	0.0	3	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10049590	Upper respiratory tract inflammation	3	0.0	3	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10029888	Obstructive bronchiolitis	2	0.0	2	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10029983	Obstructive sleep apnoea syndrome	2	0.0	1	50.0
10038738	Respiratory, thoracic and mediastinal disorders	10063076	Cough variant asthma	2	0.0	2	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10071399	Chronic eosinophilic rhinosinusitis	2	0.0	1	50.0
10038738	Respiratory, thoracic and mediastinal disorders	10076515	Combined pulmonary fibrosis and emphysema	2	0.0	1	50.0
10038738	Respiratory, thoracic and mediastinal disorders	10011224	Cough	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10014962	Eosinophilic pneumonia	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10020910	Hyperventilation	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10049459	Lymphangioleiomyomatosis	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10061768	Chronic respiratory disease	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10062952	Diffuse panbronchiolitis	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10064911	Pulmonary arterial hypertension	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10067472	Organising pneumonia	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10068318	Oropharyngeal discomfort	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10068319	Oropharyngeal pain	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10070488	Upper-airway cough syndrome	1	0.0	1	100.0
10038738	Respiratory, thoracic and mediastinal disorders	10087423	NSAID exacerbated respiratory disease	1	0.0	1	100.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10037175	Psychiatric disorders	--	--	388	5.0	339	87.4
10037175	Psychiatric disorders	10022437	Insomnia	308	4.0	269	87.3
10037175	Psychiatric disorders	10012378	Depression	39	0.5	34	87.2
10037175	Psychiatric disorders	10057666	Anxiety disorder	36	0.5	31	86.1
10037175	Psychiatric disorders	10029333	Neurosis	11	0.1	9	81.8
10037175	Psychiatric disorders	10040984	Sleep disorder	9	0.1	8	88.9
10037175	Psychiatric disorders	10039626	Schizophrenia	5	0.1	4	80.0
10037175	Psychiatric disorders	10057667	Bipolar disorder	5	0.1	5	100.0
10037175	Psychiatric disorders	10002855	Anxiety	4	0.1	4	100.0
10037175	Psychiatric disorders	10083622	Attention deficit hyperactivity disorder	3	0.0	3	100.0
10037175	Psychiatric disorders	10001297	Adjustment disorder with depressed mood	2	0.0	2	100.0
10037175	Psychiatric disorders	10033666	Panic disorder	2	0.0	2	100.0
10037175	Psychiatric disorders	10061621	Adjustment disorder	2	0.0	2	100.0
10037175	Psychiatric disorders	10001443	Affective disorder	1	0.0	1	100.0
10037175	Psychiatric disorders	10054089	Depressive symptom	1	0.0	1	100.0
10037175	Psychiatric disorders	10057852	Nicotine dependence	1	0.0	1	100.0
10037175	Psychiatric disorders	10070606	Post stroke depression	1	0.0	1	100.0
10037175	Psychiatric disorders	10077299	Rapid eye movement sleep behaviour disorder	1	0.0	1	100.0
10037175	Psychiatric disorders	10077804	Persistent depressive disorder	1	0.0	0	0.0
10037175	Psychiatric disorders	10078076	Somatic symptom disorder	1	0.0	1	100.0
10007541	Cardiac disorders	--	--	374	4.9	308	82.4
10007541	Cardiac disorders	10002383	Angina pectoris	130	1.7	112	86.2
10007541	Cardiac disorders	10003658	Atrial fibrillation	90	1.2	71	78.9
10007541	Cardiac disorders	10028596	Myocardial infarction	36	0.5	30	83.3
10007541	Cardiac disorders	10007558	Cardiac failure chronic	33	0.4	26	78.8
10007541	Cardiac disorders	10003119	Arrhythmia	19	0.2	15	78.9
10007541	Cardiac disorders	10007554	Cardiac failure	13	0.2	10	76.9
10007541	Cardiac disorders	10028600	Myocardial ischaemia	13	0.2	10	76.9
10007541	Cardiac disorders	10036759	Prinzmetal angina	11	0.1	10	90.9
10007541	Cardiac disorders	10061406	Cardiac valve disease	11	0.1	10	90.9
10007541	Cardiac disorders	10047289	Ventricular extrasystoles	8	0.1	7	87.5
10007541	Cardiac disorders	10049447	Tachyarrhythmia	6	0.1	5	83.3
10007541	Cardiac disorders	10075889	Sinus node dysfunction	6	0.1	3	50.0
10007541	Cardiac disorders	10002918	Aortic valve stenosis	5	0.1	4	80.0
10007541	Cardiac disorders	10002915	Aortic valve incompetence	4	0.1	3	75.0
10007541	Cardiac disorders	10027727	Mitral valve incompetence	4	0.1	2	50.0
10007541	Cardiac disorders	10002388	Angina unstable	3	0.0	3	100.0
10007541	Cardiac disorders	10007559	Cardiac failure congestive	3	0.0	3	100.0
10007541	Cardiac disorders	10007649	Cardiovascular disorder	3	0.0	3	100.0
10007541	Cardiac disorders	10042602	Supraventricular extrasystoles	3	0.0	1	33.3
10007541	Cardiac disorders	10042604	Supraventricular tachycardia	3	0.0	3	100.0
10007541	Cardiac disorders	10007572	Cardiac hypertrophy	2	0.0	2	100.0
10007541	Cardiac disorders	10007632	Cardiomegaly	2	0.0	2	100.0
10007541	Cardiac disorders	10040739	Sinus arrhythmia	2	0.0	2	100.0
10007541	Cardiac disorders	10044640	Tricuspid valve incompetence	2	0.0	2	100.0
10007541	Cardiac disorders	10000891	Acute myocardial infarction	1	0.0	1	100.0
10007541	Cardiac disorders	10003662	Atrial flutter	1	0.0	1	100.0
10007541	Cardiac disorders	10003673	Atrioventricular block complete	1	0.0	1	100.0
10007541	Cardiac disorders	10006580	Bundle branch block left	1	0.0	1	100.0
10007541	Cardiac disorders	10007513	Cardiac aneurysm	1	0.0	0	0.0
10007541	Cardiac disorders	10007636	Cardiomyopathy	1	0.0	1	100.0
10007541	Cardiac disorders	10020823	Hypertensive heart disease	1	0.0	1	100.0
10007541	Cardiac disorders	10033557	Palpitations	1	0.0	1	100.0
10007541	Cardiac disorders	10040752	Sinus tachycardia	1	0.0	1	100.0
10007541	Cardiac disorders	10056419	Dilated cardiomyopathy	1	0.0	1	100.0
10007541	Cardiac disorders	10058222	Hypertensive cardiomyopathy	1	0.0	1	100.0
10007541	Cardiac disorders	10061024	Cardiac disorder	1	0.0	1	100.0
10007541	Cardiac disorders	10066286	Stress cardiomyopathy	1	0.0	1	100.0
10029205	Nervous system disorders	--	--	370	4.8	332	89.7
10029205	Nervous system disorders	10008118	Cerebral infarction	70	0.9	57	81.4
10029205	Nervous system disorders	10029223	Neuralgia	51	0.7	45	88.2
10029205	Nervous system disorders	10029331	Neuropathy peripheral	50	0.6	47	94.0
10029205	Nervous system disorders	10027599	Migraine	31	0.4	30	96.8
10029205	Nervous system disorders	10013573	Dizziness	29	0.4	26	89.7
10029205	Nervous system disorders	10019211	Headache	23	0.3	22	95.7
10029205	Nervous system disorders	10036376	Post herpetic neuralgia	19	0.2	17	89.5
10029205	Nervous system disorders	10061536	Parkinson's disease	15	0.2	15	100.0
10029205	Nervous system disorders	10008334	Cervicobrachial syndrome	12	0.2	12	100.0
10029205	Nervous system disorders	10012271	Dementia Alzheimer's type	12	0.2	10	83.3
10029205	Nervous system disorders	10015037	Epilepsy	10	0.1	8	80.0
10029205	Nervous system disorders	10007687	Carotid artery stenosis	8	0.1	8	100.0
10029205	Nervous system disorders	10012267	Dementia	7	0.1	5	71.4
10029205	Nervous system disorders	10039674	Sciatica	7	0.1	7	100.0
10029205	Nervous system disorders	10067116	Carotid arteriosclerosis	7	0.1	7	100.0
10029205	Nervous system disorders	10003840	Autonomic nervous system imbalance	5	0.1	4	80.0
10029205	Nervous system disorders	10007697	Carpal tunnel syndrome	4	0.1	4	100.0
10029205	Nervous system disorders	10012680	Diabetic neuropathy	4	0.1	4	100.0
10029205	Nervous system disorders	10015496	Essential tremor	4	0.1	4	100.0
10029205	Nervous system disorders	10043269	Tension headache	4	0.1	4	100.0
10029205	Nervous system disorders	10049612	Autonomic seizure	4	0.1	3	75.0
10029205	Nervous system disorders	10008111	Cerebral haemorrhage	3	0.0	2	66.7
10029205	Nervous system disorders	10020937	Hypoesthesia	3	0.0	2	66.7
10029205	Nervous system disorders	10028417	Myasthenia gravis	3	0.0	3	100.0
10029205	Nervous system disorders	10051078	Lacunar infarction	3	0.0	2	66.7
10029205	Nervous system disorders	10070878	Cerebral small vessel ischaemic disease	3	0.0	3	100.0
10029205	Nervous system disorders	10008132	Cerebral thrombosis	2	0.0	2	100.0
10029205	Nervous system disorders	10016062	Facial paralysis	2	0.0	1	50.0
10029205	Nervous system disorders	10022758	Intracranial aneurysm	2	0.0	2	100.0
10029205	Nervous system disorders	10028047	Movayoma disease	2	0.0	2	100.0
10029205	Nervous system disorders	10044652	Trigeminal neuralgia	2	0.0	2	100.0
10029205	Nervous system disorders	10061551	Spinocerebellar disorder	2	0.0	2	100.0
10029205	Nervous system disorders	10004163	Basilar artery stenosis	1	0.0	0	0.0
10029205	Nervous system disorders	10007686	Carotid artery aneurysm	1	0.0	1	100.0
10029205	Nervous system disorders	10008034	Cerebellar infarction	1	0.0	0	0.0
10029205	Nervous system disorders	10008196	Cerebrovascular disorder	1	0.0	0	0.0
10029205	Nervous system disorders	10013983	Dystonia	1	0.0	1	100.0
10029205	Nervous system disorders	10018767	Guillain-Barre syndrome	1	0.0	0	0.0
10029205	Nervous system disorders	10028570	Myelopathy	1	0.0	1	100.0
10029205	Nervous system disorders	10042272	Subacute combined cord degeneration	1	0.0	1	100.0
10029205	Nervous system disorders	10042316	Subarachnoid haemorrhage	1	0.0	1	100.0
10029205	Nervous system disorders	10044565	Tremor	1	0.0	1	100.0
10029205	Nervous system disorders	10057268	Spinal cord paralysis	1	0.0	1	100.0
10029205	Nervous system disorders	10058920	Restless legs syndrome	1	0.0	1	100.0
10029205	Nervous system disorders	10059133	Cluster headache	1	0.0	1	100.0
10029205	Nervous system disorders	10061256	Ischaemic stroke	1	0.0	1	100.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10029205	Nervous system disorders	10063006	Facial spasm	1	0.0	1	100.0
10029205	Nervous system disorders	10064062	Neurodevelopmental disorder	1	0.0	1	100.0
10029205	Nervous system disorders	10067347	Thrombotic cerebral infarction	1	0.0	1	100.0
10029205	Nervous system disorders	10068106	Occipital neuralgia	1	0.0	1	100.0
10029205	Nervous system disorders	10072731	White matter lesion	1	0.0	1	100.0
10029205	Nervous system disorders	10077875	Neuromyelitis optica spectrum disorder	1	0.0	1	100.0
10029205	Nervous system disorders	10082308	Internal carotid artery deformity	1	0.0	1	100.0
10029205	Nervous system disorders	10087672	Vertebrobasilar artery dissection	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	--	--	207	2.7	189	91.3
10040785	Skin and subcutaneous tissue disorders	10012438	Dermatitis atopic	30	0.4	30	100.0
10040785	Skin and subcutaneous tissue disorders	10014184	Eczema	27	0.4	24	88.9
10040785	Skin and subcutaneous tissue disorders	10046735	Urticaria	26	0.3	25	96.2
10040785	Skin and subcutaneous tissue disorders	10014190	Eczema asteatotic	19	0.2	17	89.5
10040785	Skin and subcutaneous tissue disorders	10052568	Urticaria chronic	16	0.2	15	93.8
10040785	Skin and subcutaneous tissue disorders	10058130	Asteatosis	15	0.2	13	86.7
10040785	Skin and subcutaneous tissue disorders	10012431	Dermatitis	12	0.2	12	100.0
10040785	Skin and subcutaneous tissue disorders	10037087	Pruritus	9	0.1	8	88.9
10040785	Skin and subcutaneous tissue disorders	10036229	Post inflammatory pigmentation change	8	0.1	8	100.0
10040785	Skin and subcutaneous tissue disorders	10037153	Psoriasis	8	0.1	7	87.5
10040785	Skin and subcutaneous tissue disorders	10008570	Chloasma	7	0.1	6	85.7
10040785	Skin and subcutaneous tissue disorders	10012434	Dermatitis allergic	6	0.1	5	83.3
10040785	Skin and subcutaneous tissue disorders	10000496	Acne	4	0.1	3	75.0
10040785	Skin and subcutaneous tissue disorders	10001761	Alopecia areata	4	0.1	3	75.0
10040785	Skin and subcutaneous tissue disorders	10012442	Dermatitis contact	3	0.0	3	100.0
10040785	Skin and subcutaneous tissue disorders	10040943	Skin ulcer	3	0.0	3	100.0
10040785	Skin and subcutaneous tissue disorders	10058898	Hand dermatitis	3	0.0	2	66.7
10040785	Skin and subcutaneous tissue disorders	10001760	Alopecia	2	0.0	1	50.0
10040785	Skin and subcutaneous tissue disorders	10014201	Eczema nummular	2	0.0	1	50.0
10040785	Skin and subcutaneous tissue disorders	10020642	Hyperhidrosis	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10022622	Intertrigo	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10023330	Keloid scar	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10024429	Lichen planus	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10033554	Palmpoplantar keratoderma	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10034280	Pemphigus	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10037844	Rash	2	0.0	1	50.0
10040785	Skin and subcutaneous tissue disorders	10039218	Rosacea	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10039793	Seborrheic dermatitis	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10047642	Vitiligo	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10050185	Palmpoplantar pustulosis	2	0.0	2	100.0
10040785	Skin and subcutaneous tissue disorders	10081977	Senile xerosis	2	0.0	1	50.0
10040785	Skin and subcutaneous tissue disorders	10000614	Actinic keratosis	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10013786	Dry skin	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10019617	Henoch-Schönlein purpura	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10020649	Hyperkeratosis	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10020764	Hypersensitivity vasculitis	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10021247	Idiopathic urticaria	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10028690	Nail deformation	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10029263	Neurodermatitis	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10034972	Photosensitivity reaction	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10037083	Prurigo	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10048218	Xeroderma	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10048820	Urticarial vasculitis	1	0.0	1	100.0
10040785	Skin and subcutaneous tissue disorders	10062080	Pigmentation disorder	1	0.0	1	100.0
10038359	Renal and urinary disorders	--	--	202	2.6	168	83.2
10038359	Renal and urinary disorders	10020853	Hypertonic bladder	85	1.1	70	82.4
10038359	Renal and urinary disorders	10064848	Chronic kidney disease	66	0.9	54	81.8
10038359	Renal and urinary disorders	10038423	Renal cyst	10	0.1	8	80.0
10038359	Renal and urinary disorders	10061835	Diabetic nephropathy	9	0.1	8	88.9
10038359	Renal and urinary disorders	10062237	Renal impairment	8	0.1	7	87.5
10038359	Renal and urinary disorders	10029148	Nephrolithiasis	7	0.1	6	85.7
10038359	Renal and urinary disorders	10013990	Dysuria	6	0.1	6	100.0
10038359	Renal and urinary disorders	10029279	Neurogenic bladder	4	0.1	3	75.0
10038359	Renal and urinary disorders	10036018	Pollakiuria	4	0.1	3	75.0
10038359	Renal and urinary disorders	10029164	Nephrotic syndrome	3	0.0	3	100.0
10038359	Renal and urinary disorders	10077989	Ureterolithiasis	3	0.0	3	100.0
10038359	Renal and urinary disorders	10021363	IgA nephropathy	2	0.0	2	100.0
10038359	Renal and urinary disorders	10011796	Cystitis interstitial	1	0.0	1	100.0
10038359	Renal and urinary disorders	10018378	Glomerulonephritis rapidly progressive	1	0.0	1	100.0
10038359	Renal and urinary disorders	10020524	Hydronephrosis	1	0.0	1	100.0
10038359	Renal and urinary disorders	10025140	Lupus nephritis	1	0.0	1	100.0
10038359	Renal and urinary disorders	10029117	Nephritis	1	0.0	1	100.0
10038359	Renal and urinary disorders	10029151	Nephropathy	1	0.0	1	100.0
10038359	Renal and urinary disorders	10029159	Nephrosclerosis	1	0.0	1	100.0
10038359	Renal and urinary disorders	10029446	Nocturia	1	0.0	0	0.0
10038359	Renal and urinary disorders	10038428	Renal disorder	1	0.0	1	100.0
10038359	Renal and urinary disorders	10038435	Renal failure	1	0.0	1	100.0
10038359	Renal and urinary disorders	10038464	Renal hypertension	1	0.0	0	0.0
10038359	Renal and urinary disorders	10077512	End stage renal disease	1	0.0	1	100.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10014698	Endocrine disorders	--	--	195	2.5	173	88.7
10014698	Endocrine disorders	10021114	Hypothyroidism	85	1.1	79	92.9
10014698	Endocrine disorders	10049046	Autoimmune thyroiditis	43	0.6	37	86.0
10014698	Endocrine disorders	10018498	Goitre	20	0.3	19	95.0
10014698	Endocrine disorders	10018706	Graves' disease	18	0.2	17	94.4
10014698	Endocrine disorders	10020850	Hyperthyroidism	18	0.2	13	72.2
10014698	Endocrine disorders	10043781	Thyroiditis chronic	8	0.1	7	87.5
10014698	Endocrine disorders	10036692	Primary hyperaldosteronism	6	0.1	6	100.0
10014698	Endocrine disorders	10011652	Cushing's syndrome	1	0.0	1	100.0
10014698	Endocrine disorders	10012599	Diabetes insipidus	1	0.0	1	100.0
10014698	Endocrine disorders	10021067	Hypopituitarism	1	0.0	1	100.0
10014698	Endocrine disorders	10043706	Thyroid cyst	1	0.0	0	0.0
10014698	Endocrine disorders	10043709	Thyroid disorder	1	0.0	1	100.0
10014698	Endocrine disorders	10058900	Thyroid mass	1	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	--	--	179	2.3	158	88.3
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10006187	Breast cancer	33	0.4	31	93.9
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10035226	Plasma cell myeloma	12	0.2	11	91.7
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10060862	Prostate cancer	12	0.2	10	83.3
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10040907	Skin papilloma	10	0.1	10	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10046798	Uterine leiomyoma	9	0.1	7	77.8
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10009013	Chronic myeloid leukaemia	8	0.1	8	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10043744	Thyroid neoplasm	8	0.1	7	87.5
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10058467	Lung neoplasm malignant	8	0.1	5	62.5
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10025310	Lymphoma	7	0.1	5	71.4
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10000880	Acute myeloid leukaemia	5	0.1	4	80.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10009944	Colon cancer	5	0.1	5	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10025031	Lung adenocarcinoma	4	0.1	4	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10000846	Acute lymphocytic leukaemia	3	0.0	3	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10028533	Myelodysplastic syndrome	3	0.0	2	66.7
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10066474	Thyroid cancer	3	0.0	3	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10001413	Adult T-cell lymphoma/leukaemia	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10004593	Bile duct cancer	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10005003	Bladder cancer	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10005995	Bone neoplasm	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10008958	Chronic lymphocytic leukaemia	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10033609	Pancreatic carcinoma	2	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10038389	Renal cancer	2	0.0	1	50.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10046766	Uterine cancer	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10062042	Lung neoplasm	2	0.0	1	50.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10073069	Hepatic cancer	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10077465	Myeloproliferative neoplasm	2	0.0	2	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10000523	Acoustic neuroma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10001141	Adenocarcinoma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10006279	Breast neoplasm	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10008342	Cervix carcinoma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10012818	Diffuse large B-cell lymphoma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10017758	Gastric cancer	1	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10017973	Gastrointestinal lymphoma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10018814	Haemangioma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10018821	Haemangioma of liver	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10019695	Hepatic neoplasm	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10020206	Hodgkin's disease	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10024288	Leukaemia	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10025033	Lung adenocarcinoma recurrent	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10025552	Malignant fibrous histiocytoma	1	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10027191	Meningioma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10027452	Metastases to bone	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029098	Neoplasm skin	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10030155	Oesophageal carcinoma	1	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10033128	Ovarian cancer	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10033701	Papillary thyroid cancer	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10035484	Plasmacytoma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10039796	Seborrhoeic keratosis	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10041826	Squamous cell carcinoma of lung	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10050251	Castleman's disease	1	0.0	0	0.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10051066	Gastrointestinal stromal tumour	1	0.0	1	100.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10052285	Focal nodular hyperplasia	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10052399	Neuroendocrine tumour	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10053132	Lymphangiosis carcinomatosa	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10061232	Lymphoproliferative disorder	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10061538	Pituitary tumour benign	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10061850	Extranodal marginal zone B-cell lymphoma (MALT type)	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10062904	Hormone-refractory prostate cancer	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10067399	Acute biphenotypic leukaemia	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10067821	Head and neck cancer	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10070999	Intraductal papillary mucinous neoplasm	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10073071	Hepatocellular carcinoma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10085128	Follicular lymphoma	1	0.0	1	100.0
10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10086779	Carcinoid tumour in the large intestine	1	0.0	1	100.0
10021881	Infections and infestations			170	2.2	152	89.4
10021881	Infections and infestations	10047458	Viral hepatitis carrier	28	0.4	25	89.3
10021881	Infections and infestations	10009137	Chronic sinusitis	19	0.2	17	89.5
10021881	Infections and infestations	10012511	Dermatophytosis of nail	19	0.2	15	78.9
10021881	Infections and infestations	10061663	Atypical mycobacterial infection	13	0.2	11	84.6
10021881	Infections and infestations	10039083	Rhinitis	9	0.1	8	88.9
10021881	Infections and infestations	10043873	Tinea pedis	9	0.1	8	88.9
10021881	Infections and infestations	10006451	Bronchitis	8	0.1	8	100.0
10021881	Infections and infestations	10008910	Chronic hepatitis B	7	0.1	5	71.4
10021881	Infections and infestations	10040753	Sinusitis	6	0.1	6	100.0
10021881	Infections and infestations	10010741	Conjunctivitis	5	0.1	5	100.0
10021881	Infections and infestations	10017888	Gastroenteritis	5	0.1	5	100.0
10021881	Infections and infestations	10034835	Pharyngitis	5	0.1	5	100.0
10021881	Infections and infestations	10065048	Latent tuberculosis	5	0.1	5	100.0
10021881	Infections and infestations	10006448	Bronchiolitis	4	0.1	4	100.0
10021881	Infections and infestations	10006473	Bronchopulmonary aspergillosis	3	0.0	3	100.0
10021881	Infections and infestations	10008912	Chronic hepatitis C	3	0.0	2	66.7
10021881	Infections and infestations	10011781	Cystitis	3	0.0	3	100.0
10021881	Infections and infestations	10013538	Diverticulitis	3	0.0	2	66.7
10021881	Infections and infestations	10019731	Hepatitis B	3	0.0	3	100.0
10021881	Infections and infestations	10028810	Nasopharyngitis	3	0.0	3	100.0
10021881	Infections and infestations	10030154	Oesophageal candidiasis	3	0.0	3	100.0
10021881	Infections and infestations	10035664	Pneumonia	3	0.0	3	100.0
10021881	Infections and infestations	10048979	Sinobronchitis	3	0.0	3	100.0
10021881	Infections and infestations	10073755	Pneumocystis jirovecii pneumonia	3	0.0	3	100.0
10021881	Infections and infestations	10009152	Chronic tonsillitis	2	0.0	2	100.0
10021881	Infections and infestations	10019744	Hepatitis C	2	0.0	1	50.0
10021881	Infections and infestations	10037440	Pulmonary tuberculosis	2	0.0	2	100.0
10021881	Infections and infestations	10054152	Skin candida	2	0.0	1	50.0
10021881	Infections and infestations	10060889	Tinea infection	2	0.0	2	100.0
10021881	Infections and infestations	10067152	Oral herpes	2	0.0	2	100.0
10021881	Infections and infestations	10069712	HTLV-1 carrier	2	0.0	2	100.0
10021881	Infections and infestations	10000565	Acquired immunodeficiency syndrome	1	0.0	1	100.0
10021881	Infections and infestations	10001986	Amebic dysentery	1	0.0	1	100.0
10021881	Infections and infestations	10007882	Cellulitis	1	0.0	1	100.0
10021881	Infections and infestations	10012310	Dengue fever	1	0.0	1	100.0
10021881	Infections and infestations	10016936	Folliculitis	1	0.0	1	100.0
10021881	Infections and infestations	10018292	Gingivitis	1	0.0	1	100.0
10021881	Infections and infestations	10019948	Herpes simplex	1	0.0	1	100.0
10021881	Infections and infestations	10021784	Infected skin ulcer	1	0.0	1	100.0
10021881	Infections and infestations	10024968	Lower respiratory tract infection	1	0.0	1	100.0
10021881	Infections and infestations	10028781	Nasal vestibulitis	1	0.0	1	100.0
10021881	Infections and infestations	10033081	Otitis media chronic	1	0.0	1	100.0
10021881	Infections and infestations	10034539	Periodontitis	1	0.0	1	100.0
10021881	Infections and infestations	10037584	Pyelitis	1	0.0	1	100.0
10021881	Infections and infestations	10037632	Pyoderma	1	0.0	1	100.0
10021881	Infections and infestations	10044696	Tropical spastic paresis	1	0.0	1	100.0
10021881	Infections and infestations	10044755	Tuberculosis	1	0.0	1	100.0
10021881	Infections and infestations	10047470	Viral myocarditis	1	0.0	0	0.0
10021881	Infections and infestations	10047784	Vulvovaginal candidiasis	1	0.0	1	100.0
10021881	Infections and infestations	10051905	Coronavirus infection	1	0.0	1	100.0
10021881	Infections and infestations	10052748	Bacterial allergy	1	0.0	1	100.0
10021881	Infections and infestations	10052815	Antibiotic-associated colitis	1	0.0	1	100.0
10021881	Infections and infestations	10054263	Helicobacter infection	1	0.0	1	100.0
10021881	Infections and infestations	10058806	Mycobacterium avium complex infection	1	0.0	1	100.0
10021881	Infections and infestations	10058839	Enteritis infectious	1	0.0	1	100.0
10021881	Infections and infestations	10059193	Acute hepatitis B	1	0.0	1	100.0
10021881	Infections and infestations	10061354	Pneumonia fungal	1	0.0	1	100.0
10021881	Infections and infestations	10062625	Parasite allergy	1	0.0	1	100.0
10021881	Infections and infestations	10067197	Tinea manuum	1	0.0	1	100.0
10021881	Infections and infestations	10071367	Infected dermal cyst	1	0.0	1	100.0
10021881	Infections and infestations	10084268	COVID-19	1	0.0	1	100.0
10021428	Immune system disorders			150	1.9	140	93.3
10021428	Immune system disorders	10048908	Seasonal allergy	79	1.0	72	91.1
10021428	Immune system disorders	10016946	Food allergy	31	0.4	30	96.8
10021428	Immune system disorders	10013700	Drug hypersensitivity	28	0.4	26	92.9
10021428	Immune system disorders	10039486	Sarcoidosis	6	0.1	6	100.0
10021428	Immune system disorders	10077290	Mite allergy	4	0.1	4	100.0
10021428	Immune system disorders	10020751	Hypersensitivity	3	0.0	3	100.0
10021428	Immune system disorders	10001742	Allergy to animal	2	0.0	2	100.0
10021428	Immune system disorders	10018651	Graft versus host disease	2	0.0	2	100.0
10021428	Immune system disorders	10050894	Anti-neutrophil cytoplasmic antibody positive vasculitis	2	0.0	2	100.0
10021428	Immune system disorders	10066414	Allergy to metals	2	0.0	2	100.0
10021428	Immune system disorders	10002022	Amyloidosis	1	0.0	1	100.0
10021428	Immune system disorders	10002199	Anaphylactic shock	1	0.0	1	100.0
10021428	Immune system disorders	10027633	Milk allergy	1	0.0	1	100.0
10021428	Immune system disorders	10054928	Allergy to plants	1	0.0	1	100.0
10021428	Immune system disorders	10078117	Eosinophilic granulomatosis with polyangiitis	1	0.0	1	100.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10019805	Hepatobiliary disorders	--	--	141	1.8	123	87.2
10019805	Hepatobiliary disorders	10019708	Hepatic steatosis	33	0.4	31	93.9
10019805	Hepatobiliary disorders	10019670	Hepatic function abnormal	26	0.3	23	88.5
10019805	Hepatobiliary disorders	10008629	Cholelithiasis	18	0.2	17	94.4
10019805	Hepatobiliary disorders	10024670	Liver disorder	15	0.2	14	93.3
10019805	Hepatobiliary disorders	10080429	Primary biliary cholangitis	12	0.2	10	83.3
10019805	Hepatobiliary disorders	10019646	Hepatic cyst	11	0.1	9	81.8
10019805	Hepatobiliary disorders	10003827	Autoimmune hepatitis	9	0.1	5	55.6
10019805	Hepatobiliary disorders	10049704	Gallbladder polyp	8	0.1	8	100.0
10019805	Hepatobiliary disorders	10008909	Chronic hepatitis	6	0.1	6	100.0
10019805	Hepatobiliary disorders	10019641	Hepatic cirrhosis	5	0.1	5	100.0
10019805	Hepatobiliary disorders	10004637	Bile duct stone	4	0.1	2	50.0
10019805	Hepatobiliary disorders	10001627	Alcoholic liver disease	2	0.0	2	100.0
10019805	Hepatobiliary disorders	10008635	Cholestasis	2	0.0	1	50.0
10019805	Hepatobiliary disorders	10090857	Metabolic dysfunction-associated liver disease	2	0.0	2	100.0
10019805	Hepatobiliary disorders	10020732	Hyperplastic cholecystostomopathy	1	0.0	1	100.0
10019805	Hepatobiliary disorders	10057202	Biliary dilatation	1	0.0	1	100.0
10019805	Hepatobiliary disorders	10072268	Drug-induced liver injury	1	0.0	1	100.0
10019805	Hepatobiliary disorders	10090856	Metabolic dysfunction-associated steatohepatitis	1	0.0	1	100.0
10038604	Reproductive system and breast disorders	--	--	141	1.8	121	85.8
10038604	Reproductive system and breast disorders	10004446	Benign prostatic hyperplasia	98	1.3	80	81.6
10038604	Reproductive system and breast disorders	10027304	Menopausal symptoms	29	0.4	29	100.0
10038604	Reproductive system and breast disorders	10014778	Endometriosis	6	0.1	5	83.3
10038604	Reproductive system and breast disorders	10033132	Ovarian cyst	4	0.1	3	75.0
10038604	Reproductive system and breast disorders	10027339	Menstruation irregular	1	0.0	1	100.0
10038604	Reproductive system and breast disorders	10046814	Uterine prolapse	1	0.0	1	100.0
10038604	Reproductive system and breast disorders	10056268	Adenomyosis	1	0.0	1	100.0
10038604	Reproductive system and breast disorders	10061021	Breast disorder	1	0.0	1	100.0
10038604	Reproductive system and breast disorders	10085423	Heavy menstrual bleeding	1	0.0	1	100.0
10015919	Eye disorders	--	--	93	1.2	84	90.3
10015919	Eye disorders	10018304	Glaucoma	33	0.4	31	93.9
10015919	Eye disorders	10010744	Conjunctivitis allergic	24	0.3	20	83.3
10015919	Eye disorders	10013774	Dry eye	21	0.3	21	100.0
10015919	Eye disorders	10007739	Cataract	10	0.1	8	80.0
10015919	Eye disorders	10005148	Blepharitis	3	0.0	3	100.0
10015919	Eye disorders	10064930	Age-related macular degeneration	3	0.0	2	66.7
10015919	Eye disorders	10003552	Asthenopia	2	0.0	2	100.0
10015919	Eye disorders	10012689	Diabetic retinopathy	2	0.0	2	100.0
10015919	Eye disorders	10023332	Keratitis	2	0.0	2	100.0
10015919	Eye disorders	10025409	Macular degeneration	2	0.0	2	100.0
10015919	Eye disorders	10030043	Ocular hypertension	2	0.0	2	100.0
10015919	Eye disorders	10044604	Trichiasis	2	0.0	2	100.0
10015919	Eye disorders	10005159	Blepharospasm	1	0.0	1	100.0
10015919	Eye disorders	10010708	Conjunctival deposit	1	0.0	1	100.0
10015919	Eye disorders	10037263	Pterygium	1	0.0	0	0.0
10015919	Eye disorders	10038845	Retinal degeneration	1	0.0	1	100.0
10015919	Eye disorders	10038907	Retinal vein occlusion	1	0.0	1	100.0
10015919	Eye disorders	10064996	Ulcerative keratitis	1	0.0	1	100.0
10005329	Blood and lymphatic system disorders	--	--	81	1.1	74	91.4
10005329	Blood and lymphatic system disorders	10022972	Iron deficiency anaemia	44	0.6	42	95.5
10005329	Blood and lymphatic system disorders	10002034	Anaemia	7	0.1	5	71.4
10005329	Blood and lymphatic system disorders	10002817	Antiphospholipid syndrome	6	0.1	5	83.3
10005329	Blood and lymphatic system disorders	10083842	Immune thrombocytopenia	6	0.1	6	100.0
10005329	Blood and lymphatic system disorders	10002967	Aplastic anaemia	5	0.1	5	100.0
10005329	Blood and lymphatic system disorders	10058116	Nephrogenic anaemia	5	0.1	5	100.0
10005329	Blood and lymphatic system disorders	10014950	Eosinophilia	2	0.0	2	100.0
10005329	Blood and lymphatic system disorders	10024384	Leukopenia	2	0.0	2	100.0
10005329	Blood and lymphatic system disorders	10043554	Thrombocytopenia	2	0.0	2	100.0
10005329	Blood and lymphatic system disorders	10002064	Anaemia macrocytic	1	0.0	0	0.0
10005329	Blood and lymphatic system disorders	10025327	Lymphopenia	1	0.0	1	100.0
10005329	Blood and lymphatic system disorders	10029784	Normocytic anaemia	1	0.0	0	0.0
10005329	Blood and lymphatic system disorders	10033661	Pancytopenia	1	0.0	1	100.0
10005329	Blood and lymphatic system disorders	10043561	Thrombocytopenic purpura	1	0.0	1	100.0
10018065	General disorders and administration site conditions	--	--	53	0.7	52	98.1
10018065	General disorders and administration site conditions	10033371	Pain	29	0.4	29	100.0
10018065	General disorders and administration site conditions	10003549	Asthenia	3	0.0	3	100.0
10018065	General disorders and administration site conditions	10016256	Fatigue	3	0.0	3	100.0
10018065	General disorders and administration site conditions	10025482	Malaise	3	0.0	3	100.0
10018065	General disorders and administration site conditions	10049630	Oedema due to renal disease	3	0.0	3	100.0
10018065	General disorders and administration site conditions	10016059	Facial pain	2	0.0	2	100.0
10018065	General disorders and administration site conditions	10030095	Oedema	2	0.0	2	100.0
10018065	General disorders and administration site conditions	10030124	Oedema peripheral	2	0.0	1	50.0
10018065	General disorders and administration site conditions	10008479	Chest pain	1	0.0	1	100.0
10018065	General disorders and administration site conditions	10008874	Chronic fatigue syndrome	1	0.0	1	100.0
10018065	General disorders and administration site conditions	10018691	Granuloma	1	0.0	1	100.0
10018065	General disorders and administration site conditions	10037660	Pyrexia	1	0.0	1	100.0
10018065	General disorders and administration site conditions	10043458	Thirst	1	0.0	1	100.0
10018065	General disorders and administration site conditions	10048750	Axillary pain	1	0.0	1	100.0
10022891	Investigations	--	--	27	0.4	23	85.2
10022891	Investigations	10024588	Lipids abnormal	17	0.2	14	82.4
10022891	Investigations	10070218	Hepatitis C virus test positive	2	0.0	1	50.0
10022891	Investigations	10005425	Blood cholesterol increased	1	0.0	1	100.0
10022891	Investigations	10005725	Blood potassium increased	1	0.0	1	100.0
10022891	Investigations	10005750	Blood pressure increased	1	0.0	1	100.0
10022891	Investigations	10018484	Glycosylated haemoglobin increased	1	0.0	1	100.0
10022891	Investigations	10047895	Weight decreased	1	0.0	1	100.0
10022891	Investigations	10048678	Antiphospholipid antibodies positive	1	0.0	1	100.0
10022891	Investigations	10075803	Thyroid hormones decreased	1	0.0	1	100.0
10022891	Investigations	10084271	SARS-CoV-2 test positive	1	0.0	1	100.0

Table 1-5 Underlying diseases: Number of subjects by condition

As of Sep 8, 2025

Subjects included in safety analysis

SOC code	SOC	PT code	PT	Subjects included in safety analysis (n = 7707)			
				Number of subjects with underlying disease	Percentage of subjects with underlying disease (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
10042613	Surgical and medical procedures	--	--	25	0.3	24	96.0
10042613	Surgical and medical procedures	10038533	Renal transplant	7	0.1	7	100.0
10042613	Surgical and medical procedures	10002916	Aortic valve replacement	5	0.1	5	100.0
10042613	Surgical and medical procedures	10007598	Cardiac pacemaker insertion	3	0.0	3	100.0
10042613	Surgical and medical procedures	10048561	Stent placement	2	0.0	1	50.0
10042613	Surgical and medical procedures	10052086	Coronary arterial stent insertion	2	0.0	2	100.0
10042613	Surgical and medical procedures	10041642	Splenectomy	1	0.0	1	100.0
10042613	Surgical and medical procedures	10043634	Thrombosis prophylaxis	1	0.0	1	100.0
10042613	Surgical and medical procedures	10061965	Gastrectomy	1	0.0	1	100.0
10042613	Surgical and medical procedures	10061995	Heart valve replacement	1	0.0	1	100.0
10042613	Surgical and medical procedures	10064272	Bladder neoplasm surgery	1	0.0	1	100.0
10042613	Surgical and medical procedures	10066536	Allergy prophylaxis	1	0.0	1	100.0
10022117	Injury, poisoning and procedural complications	--	--	24	0.3	21	87.5
10022117	Injury, poisoning and procedural complications	10010214	Compression fracture	6	0.1	4	66.7
10022117	Injury, poisoning and procedural complications	10029183	Nerve root injury cervical	4	0.1	4	100.0
10022117	Injury, poisoning and procedural complications	10014971	Epicondylitis	2	0.0	2	100.0
10022117	Injury, poisoning and procedural complications	10050584	Confusion	2	0.0	2	100.0
10022117	Injury, poisoning and procedural complications	10069689	Spinal column injury	2	0.0	2	100.0
10022117	Injury, poisoning and procedural complications	10003441	Asbestosis	1	0.0	1	100.0
10022117	Injury, poisoning and procedural complications	10017076	Fracture	1	0.0	1	100.0
10022117	Injury, poisoning and procedural complications	10029184	Nerve root injury lumbar	1	0.0	1	100.0
10022117	Injury, poisoning and procedural complications	10042361	Subdural haematoma	1	0.0	1	100.0
10022117	Injury, poisoning and procedural complications	10052428	Wound	1	0.0	1	100.0
10022117	Injury, poisoning and procedural complications	10062544	Tooth fracture	1	0.0	1	100.0
10022117	Injury, poisoning and procedural complications	10065306	Post procedural hypothyroidism	1	0.0	0	0.0
10022117	Injury, poisoning and procedural complications	10072970	Meniscus injury	1	0.0	1	100.0
10010331	Congenital, familial and genetic disorders	--	--	17	0.2	12	70.6
10010331	Congenital, familial and genetic disorders	10020871	Hypertrophic cardiomyopathy	7	0.1	6	85.7
10010331	Congenital, familial and genetic disorders	10045261	Type IIa hyperlipidaemia	2	0.0	2	100.0
10010331	Congenital, familial and genetic disorders	10016193	Falot's tetralogy	1	0.0	1	100.0
10010331	Congenital, familial and genetic disorders	10028356	Muscular dystrophy	1	0.0	0	0.0
10010331	Congenital, familial and genetic disorders	10037339	Pulmonary artery stenosis congenital	1	0.0	1	100.0
10010331	Congenital, familial and genetic disorders	10047715	Von Willebrand's disease	1	0.0	0	0.0
10010331	Congenital, familial and genetic disorders	10051292	Protein S deficiency	1	0.0	1	100.0
10010331	Congenital, familial and genetic disorders	10060753	Type IV hyperlipidaemia	1	0.0	0	0.0
10010331	Congenital, familial and genetic disorders	10068033	Renal fusion anomaly	1	0.0	1	100.0
10010331	Congenital, familial and genetic disorders	10090911	Hereditary breast and ovarian cancer syndrome	1	0.0	0	0.0
10013993	Ear and labyrinth disorders	--	--	14	0.2	13	92.9
10013993	Ear and labyrinth disorders	10027183	Meniere's disease	6	0.1	6	100.0
10013993	Ear and labyrinth disorders	10043882	Tinnitus	3	0.0	3	100.0
10013993	Ear and labyrinth disorders	10047340	Vertigo	2	0.0	2	100.0
10013993	Ear and labyrinth disorders	10047348	Vertigo positional	2	0.0	1	50.0
10013993	Ear and labyrinth disorders	10011891	Deafness neurosensory	1	0.0	1	100.0
99999	Unknown	--	--	2	0.0	2	100.0
99999	Unknown	99999	Unknown	2	0.0	2	100.0

MedDRA/J (28.0)

Table 2-1 Vaccination status of Shingrix

As of Sep 8, 2025

Subjects included in safety analysis

		Sample size	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
Number of subjects inoculated		7707	100.0	6406	83.1
Second vaccination	No	243	3.2	156	64.2
	Yes	7464	96.8	6250	83.7
Reason for not receiving the second vaccination (Multiple choices allowed)	Occurrence of adverse events	28	0.4	26	92.9
	Pregnancy	0	0.0	0	—
	Vaccinated at another hospital	23	0.3	11	47.8
	Vaccinated with other drugs	0	0.0	0	—
	No visits after the initial vaccination	37	0.5	14	37.8
	Discontinued visits	62	0.8	40	64.5
	Reasons of the vaccinee other than the above	89	1.2	64	71.9
	Judgment of the physician other than the above	8	0.1	4	50.0
Unknown		2	0.0	2	100.0
Shingrix vaccination interval [days]	<27	1	0.0	0	0.0
Number of subjects: 7464	27≤ to <55	36	0.5	30	83.3
Mean±SD: 80.8±28.2	55≤ to <83	4989	64.7	4195	84.1
Minimum: 26	83≤ to <111	1342	17.4	1108	82.6
Median: 69.0	111≤ to <139	617	8.0	513	83.1
Maximum: 419	139≤ to <167	346	4.5	292	84.4
	167≤ to <185	105	1.4	90	85.7
	185≤	28	0.4	22	78.6
	No second vaccination	243	3.2	156	64.2

Table 2-2 Reasons for vaccination with Shingrix

As of Sep 8, 2025

Subjects included in safety analysis

		Sample size	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
Overall		7707	100.0	6406	83.1
(Multiple choices allowed)	Age at the initial vaccination with Shingrix (≥ 50 years)	1433	18.6	1191	83.1
	Immunodeficiency due to disease or treatment	9	0.1	8	88.9
	Decreased immune function due to disease or treatment	31	0.4	28	90.3
	Immune function may be compromised by disease or treatment	33	0.4	30	90.9
	The physician's judgment that the vaccination with Shingrix was necessary for reasons other than the above	20	0.3	17	85.0
	Not applicable (Prior to expansion of indications)	6225	80.8	5170	83.1
≥ 50 years old		7616	98.8	6328	83.1
(Multiple choices allowed)	Age at the initial vaccination with Shingrix (≥ 50 years)	1425	18.5	1184	83.1
	Immunodeficiency due to disease or treatment	7	0.1	6	85.7
	Decreased immune function due to disease or treatment	30	0.4	27	90.0
	Immune function may be compromised by disease or treatment	27	0.4	24	88.9
	The physician's judgment that the vaccination with Shingrix was necessary for reasons other than the above	2	0.0	1	50.0
	Not applicable (Prior to expansion of indications)	6167	80.0	5122	83.1
< 50 years old		91	1.2	78	85.7
(Multiple choices allowed)	Age at the initial vaccination with Shingrix (≥ 50 years)	8	0.1	7	87.5
	Immunodeficiency due to disease or treatment	2	0.0	2	100.0
	Decreased immune function due to disease or treatment	1	0.0	1	100.0
	Immune function may be compromised by disease or treatment	6	0.1	6	100.0
	The physician's judgment that the vaccination with Shingrix was necessary for reasons other than the above	18	0.2	16	88.9
	Not applicable (Prior to expansion of indications)	58	0.8	48	82.8

*Age represents the entered value or the value calculated from the birth year

Table 3-1 Status of initial vaccination with Shingrix

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination

Item/Category		Subjects included in safety analysis			
		Number of first dose	Percentage of doses (%)	Number of doses with ADRs	Incidence proportion of ADRs (%)
Total		7707	100.0	6158	79.9
Body temperature before Shingrix vaccination [°C]	<37.5	7211	93.6	5758	79.9
	37.5≤	0	0.0	0	—
	Mean±SD: 36.3±0.3	496	6.4	400	80.6
	Unknown	—	—	—	—
	Minimum: 34.5	—	—	—	—
	Median: 36.3	—	—	—	—
Dose volume [mL]	Maximum: 37.4	—	—	—	—
	<0.5	1	0.0	0	0.0
	0.5	7706	100.0	6158	79.9
	0.5<	0	0.0	0	—
	Minimum: 0.3	—	—	—	—
	Median: 0.5	—	—	—	—
Site of administration	Maximum: 0.5	—	—	—	—
	Upper arm Right	629	8.2	462	73.4
	Left	7028	91.2	5659	80.5
	Other Right	1	0.0	0	0.0
	Left	49	0.6	37	75.5
Route of administration	Intramuscular	7706	100.0	6157	79.9
	Other	1	0.0	1	100.0
Symptoms immediately before vaccination (e.g., poor physical condition on the day of vaccination)	No	7696	99.9	6148	79.9
	Yes	11	0.1	10	90.9

Table 3-2 Status of second vaccination with Shingrix

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

Item/Category		Subjects included in safety analysis			
		Number of second dose	Percentage of doses (%)	Number of doses with ADRs	Incidence proportion of ADRs (%)
Total		7464	100.0	5574	74.7
Body temperature before Shingrix vaccination [°C]	<37.5	7011	93.9	5239	74.7
	37.5≤	1	0.0	1	100.0
	Mean±SD: 36.3±0.3	452	6.1	334	73.9
	Unknown	—	—	—	—
	Minimum: 34.0	—	—	—	—
Median: 36.3	—	—	—	—	—
	Maximum: 37.5	—	—	—	—
	—	—	—	—	—
	—	—	—	—	—
	—	—	—	—	—
Dose volume [mL]	<0.5	2	0.0	0	0.0
	0.5	7462	100.0	5574	74.7
	Mean±SD: 0.5±0.0	0	0.0	0	—
	0.5<	—	—	—	—
	Minimum: 0.3	—	—	—	—
Median: 0.5	—	—	—	—	—
	Maximum: 0.5	—	—	—	—
	—	—	—	—	—
	—	—	—	—	—
	—	—	—	—	—
Site of administration	Upper arm Right	772	10.3	564	73.1
	Left	6645	89.0	4982	75.0
	Other Right	0	0.0	0	—
	Left	47	0.6	28	59.6
	Other	—	—	—	—
Route of administration	Intramuscular	7464	100.0	5574	74.7
	Other	0	0.0	0	—
Symptoms immediately before vaccination (e.g., poor physical condition on the day of vaccination)	No	7454	99.9	5565	74.7
	Yes	10	0.1	9	90.0

Table 3-3 Status of cumulative vaccination with Shingrix

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

Item/Category			Subjects included in safety analysis					
			Number of dose	Percentage of doses (%)	Number of doses with ADRs	Incidence proportion of ADRs (%)		
Total			15171	100.0	11732	77.3		
Body temperature before Shingrix vaccination [°C]			<37.5	14222	93.7	10997	77.3	
Number with data: 14223			37.5≤	1	0.0	1	100.0	
Mean±SD: 36.3±0.3			Unknown	948	6.2	734	77.4	
Minimum: 34.0			—	—	—	—	—	
Median: 36.3			—	—	—	—	—	
Maximum: 37.5			—	—	—	—	—	
Dose volume [mL]			<0.5	3	0.0	0	0.0	
Number with data: 15171			0.5	15168	100.0	11732	77.3	
Mean±SD: 0.5±0.0			0.5<	0	0.0	0	—	
Minimum: 0.3			—	—	—	—	—	
Median: 0.5			—	—	—	—	—	
Maximum: 0.5			—	—	—	—	—	
Site of administration			Upper arm	Right	1401	9.2	1026	73.2
				Left	13673	90.1	10641	77.8
			Other*1	Right	1	0.0	0	0.0
				Left	96	0.6	65	67.7
Route of administration			Intramuscular	15170	100.0	11731	77.3	
			Other*2	1	0.0	1	100.0	
Symptoms immediately before vaccination (e.g., poor physical condition on the day of vaccination)			No	15150	99.9	11713	77.3	
			Yes	21	0.1	19	90.5	

*1 Deltoid (n = 91), shoulder (n = 6)

*2 Subcutaneous injection (n = 1)

Table 4-1 Inoculation of vaccines other than Shingrix (first vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination			Subjects included in safety analysis (n = 7707)			
Item/Category			Sample size	Percentage of subjects treated (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
Vaccines administered during observation period (other than Shingrix)	6313476	Influenza vaccine	115	1.5	103	89.6
	GSK64128801	COVID-19 VACCINE	66	0.9	60	90.9
	6311400	Pneumococcal vaccine	29	0.4	23	79.3
	6361494	Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio combined vaccine	10	0.1	10	100.0
	6311492	Lyophilized haemophilus influenzae b conjugate vaccine (carrier protein conjugate)	9	0.1	9	100.0
	6369491	Freeze-dried live attenuated measles-rubella combined vaccine	7	0.1	6	85.7
	6313400	Freeze-dried inactivated tissue-culture rabies vaccine	5	0.1	5	100.0
	6313490	Freeze-dried inactivated tissue-culture hepatitis A vaccine	5	0.1	4	80.0
	6361491	Adsorbed diphtheria-purified pertussis-tetanus combined vaccine	5	0.1	5	100.0
	6313	Viral vaccines	4	0.1	4	100.0
	6319401	[Unified strain] Freeze-dried live-attenuated measles mumps rubella vaccine	4	0.1	4	100.0
	6319409	Mumps vaccine	3	0.0	3	100.0
	6322400	Adsorbed tetanus toxoid	3	0.0	3	100.0
	6311	Bacterial vaccines	2	0.0	2	100.0
	6313402	Recombinant precipitated hepatitis B vaccine (yeast-derived)	2	0.0	2	100.0
	6311495	Tetavalent meningococcal vaccine (diphtheria toxoid conjugate)	1	0.0	1	100.0
	6313464	Tissue-culture inactivated tick-borne encephalitis vaccine	1	0.0	1	100.0
	6313475	Recombinant adsorbed 9-valent human papillomavirus-like particle vaccine (yeast-derived)	1	0.0	1	100.0
	6313483	Inactivated polio vaccine	1	0.0	1	100.0
	6313492	Japanese encephalitis vaccine	1	0.0	1	100.0
	6313499	Yellow fever vaccine	1	0.0	1	100.0
Concomitant vaccines	6313476	Influenza vaccine	35	0.5	32	91.4
	6311400	Pneumococcal vaccine	21	0.3	19	90.5
	6361494	Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio combined vaccine	10	0.1	10	100.0
	6311492	Lyophilized haemophilus influenzae b conjugate vaccine (carrier protein conjugate)	9	0.1	9	100.0
	6361491	Adsorbed diphtheria-purified pertussis-tetanus combined vaccine	5	0.1	5	100.0
	6313	Viral vaccines	3	0.0	3	100.0
	6313400	Freeze-dried inactivated tissue-culture rabies vaccine	3	0.0	3	100.0
	6313490	Freeze-dried inactivated tissue-culture hepatitis A vaccine	3	0.0	2	66.7
	6319409	Mumps vaccine	3	0.0	3	100.0
	6369491	Freeze-dried live attenuated measles-rubella combined vaccine	3	0.0	2	66.7
	6319401	[Unified strain] Freeze-dried live-attenuated measles mumps rubella vaccine	2	0.0	2	100.0
	6322400	Adsorbed tetanus toxoid	2	0.0	2	100.0
	6311	Bacterial vaccines	1	0.0	1	100.0
	6311495	Tetavalent meningococcal vaccine (diphtheria toxoid conjugate)	1	0.0	1	100.0
	6313475	Recombinant adsorbed 9-valent human papillomavirus-like particle vaccine (yeast-derived)	1	0.0	1	100.0
	6313492	Japanese encephalitis vaccine	1	0.0	1	100.0

Table 4-2 Inoculation of vaccines other than Shingrix (second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

Item/Category			Subjects included in safety analysis (n = 7464)			
			Sample size	Percentage of subjects treated (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
Vaccines administered during observation period (other than Shingrix)	GSK64128801	COVID-19 VACCINE	101	1.4	80	79.2
	6313476	Influenza vaccine	78	1.0	63	80.8
	6311400	Pneumococcal vaccine	11	0.1	7	63.6
	6322400	Adsorbed tetanus toxoid	3	0.0	3	100.0
	6361491	Adsorbed diphtheria-purified pertussis-tetanus combined vaccine	3	0.0	2	66.7
	6313402	Recombinant precipitated hepatitis B vaccine (yeast-derived)	1	0.0	1	100.0
	6313464	Tissue-culture inactivated tick-borne encephalitis vaccine	1	0.0	1	100.0
	6313475	Recombinant adsorbed 9-valent human papillomavirus-like particle vaccine (yeast-derived)	1	0.0	1	100.0
	6313490	Freeze-dried inactivated tissue-culture hepatitis A vaccine	1	0.0	1	100.0
	6319409	Mumps vaccine	1	0.0	1	100.0
Concomitant vaccines	6369491	Freeze-dried live attenuated measles-rubella combined vaccine	1	0.0	1	100.0
	6313476	Influenza vaccine	19	0.3	16	84.2
	6311400	Pneumococcal vaccine	6	0.1	4	66.7
	6322400	Adsorbed tetanus toxoid	3	0.0	3	100.0
	6361491	Adsorbed diphtheria-purified pertussis-tetanus combined vaccine	3	0.0	2	66.7
	6313402	Recombinant precipitated hepatitis B vaccine (yeast-derived)	1	0.0	1	100.0
	6313464	Tissue-culture inactivated tick-borne encephalitis vaccine	1	0.0	1	100.0
	6313475	Recombinant adsorbed 9-valent human papillomavirus-like particle vaccine (yeast-derived)	1	0.0	1	100.0
	6313490	Freeze-dried inactivated tissue-culture hepatitis A vaccine	1	0.0	1	100.0
	6319409	Mumps vaccine	1	0.0	1	100.0
	6369491	Freeze-dried live attenuated measles-rubella combined vaccine	1	0.0	1	100.0
	GSK64128801	COVID-19 VACCINE	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
218	Hyperlipidemia agents	—	1142	14.8	1016	89.0
2189017	Hyperlipidemia agents	Rosuvastatin Calcium	392	5.1	356	90.8
2189016	Hyperlipidemia agents	Pravastatin Calcium	273	3.5	243	89.0
2189015	Hyperlipidemia agents	Atorvastatin Calcium Hydrate	216	2.8	193	89.4
2189010	Hyperlipidemia agents	Pravastatin Sodium	101	1.3	90	89.1
2189018	Hyperlipidemia agents	Ezetimibe	59	0.8	53	89.8
2189019	Hyperlipidemia agents	Omega-3-acid ethyl esters	51	0.7	42	82.4
2183007	Hyperlipidemia agents	Pemafibrate	46	0.6	39	84.8
2183006	Hyperlipidemia agents	Fenofibrate	21	0.3	18	85.7
2183005	Hyperlipidemia agents	Bezafibrate	19	0.2	14	73.7
2189011	Hyperlipidemia agents	Simvastatin	19	0.2	16	84.2
2189102	Hyperlipidemia agents	Ezetimibe and rosuvastatin calcium combination drug	18	0.2	16	88.9
2189012	Hyperlipidemia agents	Fluvastatin Sodium	11	0.1	10	90.9
2189101	Hyperlipidemia agents	Ezetimibe/atorvastatin calcium hydrate combination drug	5	0.1	4	80.0
2189	Hyperlipidemia agents	Hyperlipidemia agents-Other	1	0.0	1	100.0
2183002	Hyperlipidemia agents	Clofibrate	1	0.0	1	100.0
2189006	Hyperlipidemia agents	Polynephosphatidyl Choline	1	0.0	1	100.0
2189008	Hyperlipidemia agents	Probucol	1	0.0	1	100.0
2189014	Hyperlipidemia agents	Colestimide	1	0.0	1	100.0
2189103	Hyperlipidemia agents	Pravastatin Calcium Hydrate/Ezetimibe Combination	1	0.0	1	100.0
214	Antihypertensives	—	892	11.6	768	86.1
2149044	Antihypertensives	Olmesartan Medoxomil	118	1.5	99	83.9
2149040	Antihypertensives	Candesartan Cilexetil	113	1.5	99	87.6
2149042	Antihypertensives	Telmisartan	109	1.4	98	89.9
2149048	Antihypertensives	Azilsartan	98	1.3	87	88.8
2149032	Antihypertensives	Carvedilol	57	0.7	50	87.7
2149041	Antihypertensives	Valsartan	53	0.7	42	79.2
2149116	Antihypertensives	Candesartan Cilexetil/Amlodipine Besilate Combination	47	0.6	41	87.2
2149117	Antihypertensives	Telmisartan/Amlodipine Besilate Combination	47	0.6	41	87.2
2149121	Antihypertensives	Azilsartan/Amlodipine Besilate Combination	45	0.6	36	80.0
2149037	Antihypertensives	Cilnidipine	38	0.5	33	86.8
2149118	Antihypertensives	Irbesartan/Amlodipine Besilate Combination	35	0.5	32	91.4
2149039	Antihypertensives	Losartan potassium	33	0.4	28	84.8
2149046	Antihypertensives	Irbesartan	28	0.4	24	85.7
2144002	Antihypertensives	Enalapril Maleate	17	0.2	12	70.6
2149049	Antihypertensives	Esaxerenone	17	0.2	13	76.5
2149114	Antihypertensives	Valsartan/Amlodipine Besilate Combination	17	0.2	15	88.2
2149026	Antihypertensives	Doxazosin Mesilate	16	0.2	15	93.8
2149045	Antihypertensives	Eplerenone	14	0.2	12	85.7
2149012	Antihypertensives	Indapamide	13	0.2	11	84.6
2149043	Antihypertensives	Azelidipine	13	0.2	11	84.6
2149115	Antihypertensives	Olmesartan Medoxomil/Azelidipine Combination	13	0.2	10	76.9
2149110	Antihypertensives	Losartan Potassium/Hydrochlorothiazide Combination	11	0.1	8	72.7
2149111	Antihypertensives	Candesartan Cilexetil/Hydrochlorothiazide Combination	9	0.1	7	77.8
2144012	Antihypertensives	Perindopril Erbumine	8	0.1	7	87.5
2144008	Antihypertensives	Imidapril Hydrochloride	7	0.1	6	85.7
2149027	Antihypertensives	Manidipine Hydrochloride	6	0.1	6	100.0
2149113	Antihypertensives	Telmisartan/Hydrochlorothiazide Combination	5	0.1	4	80.0
2149020	Antihypertensives	Urapidil	4	0.1	3	75.0
2149120	Antihypertensives	Valsartan/Cilnidipine Combination	4	0.1	3	75.0
2149700	Antihypertensives	Bisoprolol	4	0.1	2	50.0
2149029	Antihypertensives	Celiprolol Hydrochloride	3	0.0	3	100.0
2149119	Antihypertensives	Irbesartan/Trichlormethiazide Combination	3	0.0	3	100.0
2149019	Antihypertensives	Nicardipine Hydrochloride	2	0.0	2	100.0
2149122	Antihypertensives	Telmisartan/Amlodipine Besilate/Hydrochlorothiazide Combination	2	0.0	2	100.0
214	Antihypertensives	Antihypertensives	1	0.0	1	100.0
2144003	Antihypertensives	Alacepril	1	0.0	1	100.0
2144006	Antihypertensives	Lisinopril Hydrate	1	0.0	1	100.0
2145001	Antihypertensives	Methyldopa Hydrate	1	0.0	1	100.0
2149022	Antihypertensives	Nitvadipine	1	0.0	1	100.0
2149047	Antihypertensives	Aliskiren Fumarate	1	0.0	1	100.0
2149112	Antihypertensives	Valsartan/Hydrochlorothiazide Combination	1	0.0	1	100.0
399	Other agents affecting metabolism-Miscellaneous	—	764	9.9	703	92.0
3999016	Other agents affecting metabolism-Miscellaneous	Methotrexate	292	3.8	277	94.9
3999031	Other agents affecting metabolism-Miscellaneous	Iguratomid	92	1.2	85	92.4
3999014	Other agents affecting metabolism-Miscellaneous	Tacrolimus Hydrate	62	0.8	60	96.8
3999018	Other agents affecting metabolism-Miscellaneous	Alendronate Sodium Hydrate	58	0.8	55	94.8
3999048	Other agents affecting metabolism-Miscellaneous	Upadacitinib Hydrate	54	0.7	48	88.9
3999019	Other agents affecting metabolism-Miscellaneous	Sodium Risedronate Hydrate	52	0.7	45	86.5
3999026	Other agents affecting metabolism-Miscellaneous	Minodronic Acid Hydrate	43	0.6	41	95.3
3999043	Other agents affecting metabolism-Miscellaneous	Baricitinib	43	0.6	38	88.4
3999027	Other agents affecting metabolism-Miscellaneous	Bazedoxifene Acetate	40	0.5	38	95.0
3999021	Other agents affecting metabolism-Miscellaneous	Raloxifene Hydrochloride	36	0.5	31	86.1
3999433	Other agents affecting metabolism-Miscellaneous	Golimumab (Genetical Recombination)	31	0.4	29	93.5
3999435	Other agents affecting metabolism-Miscellaneous	Denosumab (Genetical Recombination)	30	0.4	29	96.7
3999408	Other agents affecting metabolism-Miscellaneous	Purified sodium hyaluronate	28	0.4	26	92.9
3999053	Other agents affecting metabolism-Miscellaneous	Filgotinib Maleate	25	0.3	20	80.0
3999429	Other agents affecting metabolism-Miscellaneous	Abatacept (Genetical Recombination)	25	0.3	24	96.0
3999426	Other agents affecting metabolism-Miscellaneous	Adalimumab (Genetical Recombination)	24	0.3	20	83.3
3999040	Other agents affecting metabolism-Miscellaneous	Ibandronate Sodium Hydrate	22	0.3	20	90.9
3999424	Other agents affecting metabolism-Miscellaneous	Financcept (Genetical Recombination)	22	0.3	22	100.0
3999444	Other agents affecting metabolism-Miscellaneous	Sarilumab (Genetical Recombination)	18	0.2	15	83.3
39992001	Other agents affecting metabolism-Miscellaneous	Adenosine Triphosphate Disodium Hydrate	16	0.2	14	87.5
3999002	Other agents affecting metabolism-Miscellaneous	Mizoribine	16	0.2	14	87.5
3999034	Other agents affecting metabolism-Miscellaneous	Tofacitinib Citrate	14	0.2	13	92.9
3999017	Other agents affecting metabolism-Miscellaneous	Myxophenolate Mofetil	9	0.1	9	100.0
3999004	Other agents affecting metabolism-Miscellaneous	Ciclosporin	7	0.1	7	100.0
3999437	Other agents affecting metabolism-Miscellaneous	Certolizumab Pegol (Genetical Recombination)	7	0.1	7	100.0
3999438	Other agents affecting metabolism-Miscellaneous	Ibandronate Sodium Hydrate	7	0.1	7	100.0
3999038	Other agents affecting metabolism-Miscellaneous	Hydroxychloroquine Sulfate	6	0.1	6	100.0
3999046	Other agents affecting metabolism-Miscellaneous	Peficitinib Hydrobromide	6	0.1	6	100.0
3999449	Other agents affecting metabolism-Miscellaneous	Romosozumab (Genetical Recombination)	6	0.1	6	100.0
3999003	Other agents affecting metabolism-Miscellaneous	Camostat Mesilate	5	0.1	5	100.0
3999020	Other agents affecting metabolism-Miscellaneous	Leflunomide	4	0.1	2	50.0
3999022	Other agents affecting metabolism-Miscellaneous	Everolimus	4	0.1	4	100.0
3999467	Other agents affecting metabolism-Miscellaneous	Ozoralizumab (Genetical Recombination)	4	0.1	2	50.0
3999005	Other agents affecting metabolism-Miscellaneous	Azathioprine	3	0.0	3	100.0
3999445	Other agents affecting metabolism-Miscellaneous	Belimumab (Genetical Recombination)	3	0.0	3	100.0
3999468	Other agents affecting metabolism-Miscellaneous	Methotrexate	3	0.0	2	66.7
3999028	Other agents affecting metabolism-Miscellaneous	Eltrombopag Olamine	2	0.0	2	100.0
3999039	Other agents affecting metabolism-Miscellaneous	Nintedanib Ethanesulfonate	2	0.0	2	100.0
3999042	Other agents affecting metabolism-Miscellaneous	Apremilast	2	0.0	2	100.0
3999401	Other agents affecting metabolism-Miscellaneous	Elcatonin	2	0.0	2	100.0
3999442	Other agents affecting metabolism-Miscellaneous	Ixekizumab (Genetical Recombination)	2	0.0	1	50.0
3999006	Other agents affecting metabolism-Miscellaneous	L-cysteine	1	0.0	1	100.0
3999008	Other agents affecting metabolism-Miscellaneous	Ipriflavone	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
3999050	Other agents affecting metabolism-Miscellaneous	Vadadustat	1	0.0	1	100.0
3999419	Other agents affecting metabolism-Miscellaneous	Alendronate Sodium Hydrate	1	0.0	1	100.0
3999425	Other agents affecting metabolism-Miscellaneous	Darbepoetin Alfa (Genetical Recombination)	1	0.0	1	100.0
3999439	Other agents affecting metabolism-Miscellaneous	Secukinumab (Genetical Recombination)	1	0.0	1	100.0
3999441	Other agents affecting metabolism-Miscellaneous	Brodalumab (Genetical Recombination)	1	0.0	1	100.0
3999448	Other agents affecting metabolism-Miscellaneous	Etanercept (Genetical Recombination) [Biosimilar 1]	1	0.0	0	0.0
3999457	Other agents affecting metabolism-Miscellaneous	Adalimumab (Genetical Recombination) [Biosimilar 1]	1	0.0	1	100.0
3999462	Other agents affecting metabolism-Miscellaneous	Anifrolumab (Genetical Recombination)	1	0.0	1	100.0
232	Peptic ulcer agents	—	698	9.1	622	89.1
2329029	Peptic ulcer agents	Esomeprazole Magnesium Hydrate	161	2.1	132	82.0
2329030	Peptic ulcer agents	Vonoprazan Fumarate	156	2.0	144	92.3
2329021	Peptic ulcer agents	Rebamipide	150	1.9	138	92.0
2329023	Peptic ulcer agents	Lansoprazole	97	1.3	82	84.5
2329028	Peptic ulcer agents	Rabeprazole Sodium	62	0.8	57	91.9
2325003	Peptic ulcer agents	Famotidine	57	0.7	56	98.2
2329012	Peptic ulcer agents	Teprenone	34	0.4	29	85.3
2329022	Peptic ulcer agents	Omeprazole	23	0.3	21	91.3
2329020	Peptic ulcer agents	Irsogladine Maleate	13	0.2	13	100.0
2329027	Peptic ulcer agents	Polaprezinc	13	0.2	13	100.0
2329009	Peptic ulcer agents	Sulpiride	9	0.1	8	88.9
2329026	Peptic ulcer agents	Ecabet Sodium Hydrate	9	0.1	9	100.0
2329122	Peptic ulcer agents	Sodium Gualeate Hydrate/L-glutamine	9	0.1	8	88.9
2325006	Peptic ulcer agents	Lafutidine	7	0.1	7	100.0
2323001	Peptic ulcer agents	Sodium Gualeate Hydrate	3	0.0	3	100.0
2325005	Peptic ulcer agents	Nizatidine	3	0.0	3	100.0
2329008	Peptic ulcer agents	Sucralfate Hydrate	3	0.0	3	100.0
2329015	Peptic ulcer agents	Tioxoxide	3	0.0	2	66.7
2329116	Peptic ulcer agents	Sodium Alginate	3	0.0	3	100.0
2321001	Peptic ulcer agents	Methylmethionine Sulfonium Chloride	2	0.0	2	100.0
2325001	Peptic ulcer agents	Cimetidine	1	0.0	1	100.0
2325004	Peptic ulcer agents	Roxatidine Acetate Hydrochloride	1	0.0	0	0.0
2329002	Peptic ulcer agents	Aldiosa	1	0.0	1	100.0
2329024	Peptic ulcer agents	Misoprostol	1	0.0	1	100.0
114	Antipyretics, analgesics, and anti-inflammatory agents	—	682	8.8	656	96.2
1141007	Antipyretics, analgesics, and anti-inflammatory agents	Acetaminophen	257	3.3	256	99.6
1149019	Antipyretics, analgesics, and anti-inflammatory agents	Loxoprofen Sodium Hydrate	250	3.2	242	96.8
1149037	Antipyretics, analgesics, and anti-inflammatory agents	Celecoxib	80	1.0	71	88.8
1149117	Antipyretics, analgesics, and anti-inflammatory agents	Tramadol Hydrochloride/Acetaminophen Combination	45	0.6	42	93.3
1149001	Antipyretics, analgesics, and anti-inflammatory agents	Ibuprofen	42	0.5	42	100.0
1147002	Antipyretics, analgesics, and anti-inflammatory agents	Diclofenac Sodium	20	0.3	17	85.0
1149023	Antipyretics, analgesics, and anti-inflammatory agents	Extract from inflamed cutaneous tissue of rabbits inoculated with vaccinia virus	14	0.2	13	92.9
1149038	Antipyretics, analgesics, and anti-inflammatory agents	Tramadol Hydrochloride	14	0.2	14	100.0
1149502	Antipyretics, analgesics, and anti-inflammatory agents	Sodium Salicylate/Dibucaine Combination	10	0.1	9	90.0
1149032	Antipyretics, analgesics, and anti-inflammatory agents	Etodolac	8	0.1	7	87.5
1147700	Antipyretics, analgesics, and anti-inflammatory agents	Diclofenac Sodium	5	0.1	5	100.0
1149035	Antipyretics, analgesics, and anti-inflammatory agents	Meloxicam	4	0.1	4	100.0
1149103	Antipyretics, analgesics, and anti-inflammatory agents	Pyrazolone-based antipyretic, analgesic, and anti-inflammatory combination drug (2)	4	0.1	4	100.0
1143002	Antipyretics, analgesics, and anti-inflammatory agents	Aspirin	3	0.0	3	100.0
1149007	Antipyretics, analgesics, and anti-inflammatory agents	Naproxen	3	0.0	2	66.7
1149031	Antipyretics, analgesics, and anti-inflammatory agents	Actarit	3	0.0	2	66.7
1149036	Antipyretics, analgesics, and anti-inflammatory agents	Lomoxicam	3	0.0	3	100.0
114	Antipyretics, analgesics, and anti-inflammatory agents	—	2	0.0	2	100.0
1141005	Antipyretics, analgesics, and anti-inflammatory agents	Mefernamic Acid	1	0.0	1	100.0
1143005	Antipyretics, analgesics, and anti-inflammatory agents	Eibenzamide	1	0.0	1	100.0
1145005	Antipyretics, analgesics, and anti-inflammatory agents	Indometacin Farnesil	1	0.0	1	100.0
1149005	Antipyretics, analgesics, and anti-inflammatory agents	Ketoprofen	1	0.0	1	100.0
1149010	Antipyretics, analgesics, and anti-inflammatory agents	Pranoprofen	1	0.0	1	100.0
1149029	Antipyretics, analgesics, and anti-inflammatory agents	Zaltoprofen	1	0.0	1	100.0
1149030	Antipyretics, analgesics, and anti-inflammatory agents	Ampiroxicam	1	0.0	1	100.0
1149116	Antipyretics, analgesics, and anti-inflammatory agents	Pyrazolone-based antipyretic, analgesic, and anti-inflammatory combination drugs (4)	1	0.0	1	100.0
1149601	Antipyretics, analgesics, and anti-inflammatory agents	Extract from inflamed cutaneous tissue of rabbits inoculated with vaccinia virus	1	0.0	1	100.0
217	Vasodilators	—	678	8.8	594	87.6
2171022	Vasodilators	Amlodipine Besilate	512	6.6	452	88.3
2171014	Vasodilators	Nifedipine	97	1.3	78	80.4
2171021	Vasodilators	Benidipine Hydrochloride	38	0.5	36	94.7
2171006	Vasodilators	Diltiazem Hydrochloride	18	0.2	15	83.3
2171017	Vasodilators	Nicorandil	13	0.2	12	92.3
2171008	Vasodilators	Verapamil Hydrochloride	7	0.1	6	85.7
2171011	Vasodilators	Isosorbide Dinitrate	7	0.1	6	85.7
2171023	Vasodilators	Isosorbide Mononitrate	6	0.1	5	83.3
2171018	Vasodilators	Nitroglycerin	5	0.1	5	100.0
2171700	Vasodilators	Isosorbide Dinitrate	4	0.1	4	100.0
2171005	Vasodilators	Dilazep Hydrochloride Hydrate	2	0.0	2	100.0
2171010	Vasodilators	Dipyridamole	1	0.0	1	100.0
2171701	Vasodilators	Nitroglycerin	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
449	Allergic agents-Miscellaneous	—	398	5.2	376	94.5
4490026	Allergic agents-Miscellaneous	Montelukast Sodium	79	1.0	77	97.5
4490023	Allergic agents-Miscellaneous	Fexofenadine Hydrochloride	67	0.9	66	98.5
4490028	Allergic agents-Miscellaneous	Levocetirizine Hydrochloride	52	0.7	48	92.3
4490033	Allergic agents-Miscellaneous	Bilastine	47	0.6	43	91.5
4490022	Allergic agents-Miscellaneous	Bepotastine Besilate	45	0.6	42	93.3
4490025	Allergic agents-Miscellaneous	Olopatadine Hydrochloride	41	0.5	37	90.2
4490014	Allergic agents-Miscellaneous	Epinalastine Hydrochloride	27	0.4	27	100.0
4490032	Allergic agents-Miscellaneous	Desloratadine	23	0.3	23	100.0
4490034	Allergic agents-Miscellaneous	Rupatadine Fumarate	20	0.3	19	95.0
4490035	Allergic agents-Miscellaneous	Japanese cedar pollen extract	13	0.2	12	92.3
4490019	Allergic agents-Miscellaneous	Ebastine	11	0.1	10	90.9
4490027	Allergic agents-Miscellaneous	Loratadine	11	0.1	11	100.0
4490017	Allergic agents-Miscellaneous	Pranlukast Hydrate	7	0.1	6	85.7
4490016	Allergic agents-Miscellaneous	Suplatast Tosilate	5	0.1	5	100.0
4490020	Allergic agents-Miscellaneous	Cetirizine Hydrochloride	4	0.1	2	50.0
4490031	Allergic agents-Miscellaneous	Allergen Extract	4	0.1	4	100.0
4490002	Allergic agents-Miscellaneous	Tranilast	2	0.0	2	100.0
4490100	Allergic agents-Miscellaneous	Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride Combination	2	0.0	2	100.0
4490013	Allergic agents-Miscellaneous	Emedastine Fumarate	1	0.0	1	100.0
4490021	Allergic agents-Miscellaneous	Ramatroban	1	0.0	1	100.0
4490405	Allergic agents-Miscellaneous	Dupilumab (Genetical Recombination)	1	0.0	1	100.0
4490700	Allergic agents-Miscellaneous	Emedastine Fumarate	1	0.0	1	100.0
396	Antidiabetic agents	—	380	4.9	338	88.9
3962002	Antidiabetic agents	Metformin Hydrochloride	137	1.8	128	93.4
3969010	Antidiabetic agents	Sitagliptin Phosphate Hydrate	60	0.8	53	88.3
3969023	Antidiabetic agents	Empagliflozin	38	0.5	34	89.5
3961008	Antidiabetic agents	Glimepiride	37	0.5	32	86.5
3969104	Antidiabetic agents	Vildagliptin/Metformin Hydrochloride Combination	36	0.5	33	91.7
3969019	Antidiabetic agents	Dapagliflozin Propylene Glycolate Hydrate	34	0.4	29	85.3
3969014	Antidiabetic agents	Linagliptin	30	0.4	28	93.3
3969015	Antidiabetic agents	Teneligliptin Hydrobromide Hydrate	26	0.3	22	84.6
3969004	Antidiabetic agents	Voglibose	22	0.3	20	90.9
3969009	Antidiabetic agents	Migliitol	22	0.3	18	81.8
3969021	Antidiabetic agents	Tofogliflozin Hydrate	20	0.3	15	75.0
3969012	Antidiabetic agents	Alogliptin Benzoate	18	0.2	16	88.9
3969108	Antidiabetic agents	Empagliflozin/Linagliptin Combination	18	0.2	17	94.4
3969011	Antidiabetic agents	Vildagliptin	17	0.2	14	82.4
3969008	Antidiabetic agents	Mitiglinide Calcium Hydrate	15	0.2	13	86.7
3969022	Antidiabetic agents	Canagliflozin Hydrate	15	0.2	13	86.7
3969007	Antidiabetic agents	Pioglitazone Hydrochloride	13	0.2	11	84.6
3969020	Antidiabetic agents	Luseogliflozin Hydrate	13	0.2	10	76.9
3969106	Antidiabetic agents	Teneligliptin Hydrobromide Hydrate/Canagliflozin Hydrate Combination	12	0.2	9	75.0
3969018	Antidiabetic agents	Ipragliflozin L-proline	10	0.1	9	90.0
3969102	Antidiabetic agents	Mitiglinide Calcium Hydrate/Voglibose Combination	10	0.1	8	80.0
3969013	Antidiabetic agents	Repaglinide	8	0.1	8	100.0
3969017	Antidiabetic agents	Saxagliptin Hydrate	7	0.1	7	100.0
3969105	Antidiabetic agents	Alogliptin Benzoate/Metformin Hydrochloride Combination	7	0.1	6	85.7
3961007	Antidiabetic agents	Gliclazide	6	0.1	5	83.3
3969109	Antidiabetic agents	Anagliptin/Metformin Hydrochloride Combination	6	0.1	5	83.3
3969026	Antidiabetic agents	Ineglimine Hydrochloride	5	0.1	5	100.0
3969107	Antidiabetic agents	Sitagliptin Phosphate Hydrate/Ipragliflozin L-Proline Combination	5	0.1	5	100.0
3969003	Antidiabetic agents	Acarbose	4	0.1	3	75.0
3969016	Antidiabetic agents	Anagliptin	4	0.1	4	100.0
3969025	Antidiabetic agents	Omargliptin	4	0.1	3	75.0
3969500	Antidiabetic agents	Insulin Degludec (Genetical Recombination)/Liraglutide (Genetical Recombination) Combination	4	0.1	4	100.0
3969006	Antidiabetic agents	Nateglinide	3	0.0	3	100.0
3969024	Antidiabetic agents	Trelagliptin Succinate	2	0.0	2	100.0
3969103	Antidiabetic agents	Alogliptin Benzoate/Pioglitazone Hydrochloride Combination	2	0.0	2	100.0
3961003	Antidiabetic agents	Glibenclamide	1	0.0	0	0.0
3969100	Antidiabetic agents	Pioglitazone Hydrochloride/Metformin Hydrochloride Combination	1	0.0	1	100.0
3969101	Antidiabetic agents	Pioglitazone Hydrochloride/Glimepiride Combination	1	0.0	0	0.0
339	Blood and body fluid agents-Miscellaneous	—	330	4.3	285	86.4
3399007	Blood and body fluid agents-Miscellaneous	Aspirin	108	1.4	88	81.5
3399004	Blood and body fluid agents-Miscellaneous	Ethyl Icosapentate	72	0.9	61	84.7
3399008	Blood and body fluid agents-Miscellaneous	Clopidogrel Sulfate	49	0.6	41	83.7
3399003	Blood and body fluid agents-Miscellaneous	Limaprost Alfadex	46	0.6	38	82.6
3399100	Blood and body fluid agents-Miscellaneous	Aspirin/Dialuminate	39	0.5	39	100.0
3399002	Blood and body fluid agents-Miscellaneous	Cilostazol	19	0.2	18	94.7
3399102	Blood and body fluid agents-Miscellaneous	Aspirin/Lansoprazole Combination	12	0.2	10	83.3
3399009	Blood and body fluid agents-Miscellaneous	Prasugrel Hydrochloride	6	0.1	4	66.7
3399005	Blood and body fluid agents-Miscellaneous	Beraprost Sodium	5	0.1	5	100.0
3399006	Blood and body fluid agents-Miscellaneous	Sarpogrelate Hydrochloride	5	0.1	5	100.0
3399001	Blood and body fluid agents-Miscellaneous	Ticlopidine Hydrochloride	3	0.0	2	66.7
3399101	Blood and body fluid agents-Miscellaneous	Clopidogrel Sulfate/Aspirin	1	0.0	1	100.0
3399103	Blood and body fluid agents-Miscellaneous	Aspirin/Vonopranzan Fumarate Combination	1	0.0	0	0.0
311	Vitamins A and D preparations	—	283	3.7	256	90.5
3112006	Vitamins A and D preparations	Eldecalcitol	202	2.6	183	90.6
3112001	Vitamins A and D preparations	Alfalcidol	79	1.0	71	89.9
3112004	Vitamins A and D preparations	Calcitriol	2	0.0	2	100.0
3119001	Vitamins A and D preparations	Etiolate	1	0.0	1	100.0
112	Hypnotics and sedatives, anxiolytics	—	245	3.2	213	86.9
1129009	Hypnotics and sedatives, anxiolytics	Zolpidem Tartrate	88	1.1	77	87.5
1124009	Hypnotics and sedatives, anxiolytics	Brotizolam	57	0.7	48	84.2
1129010	Hypnotics and sedatives, anxiolytics	Eszopiclone	38	0.5	30	78.9
1124007	Hypnotics and sedatives, anxiolytics	Triazolam	19	0.2	16	84.2
1124023	Hypnotics and sedatives, anxiolytics	Alprazolam	17	0.2	14	82.4
1124008	Hypnotics and sedatives, anxiolytics	Flunitrazepam	10	0.1	10	100.0
1124017	Hypnotics and sedatives, anxiolytics	Diazepam	8	0.1	8	100.0
1124029	Hypnotics and sedatives, anxiolytics	Ethyl Loflazepate	7	0.1	6	85.7
1124020	Hypnotics and sedatives, anxiolytics	Bromazepam	4	0.1	4	100.0
1124022	Hypnotics and sedatives, anxiolytics	Lorazepam	4	0.1	2	50.0
1124028	Hypnotics and sedatives, anxiolytics	Chlordiazepoxide	3	0.0	3	100.0
1129006	Hypnotics and sedatives, anxiolytics	Rilmazafone Hydrochloride Hydrate	3	0.0	3	100.0
1129007	Hypnotics and sedatives, anxiolytics	Zopiclone	3	0.0	3	100.0
1124001	Hypnotics and sedatives, anxiolytics	Estazolam	2	0.0	2	100.0
1124030	Hypnotics and sedatives, anxiolytics	Quazepam	2	0.0	2	100.0
1124010	Hypnotics and sedatives, anxiolytics	Lormetazepam	1	0.0	1	100.0
1124014	Hypnotics and sedatives, anxiolytics	Cloazolam	1	0.0	1	100.0
1125004	Hypnotics and sedatives, anxiolytics	Phenobarbital	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
245	Adrenal hormone preparations	—	237	3.1	209	88.2
2456002	Adrenal hormone preparations	Prednisolone	204	2.6	181	88.7
2456003	Adrenal hormone preparations	Methylprednisolone	15	0.2	14	93.3
2454002	Adrenal hormone preparations	Dexamethasone	8	0.1	8	100.0
2459100	Adrenal hormone preparations	Betamethasone/d-Chlorpheniramine Maleate	5	0.1	3	60.0
2454407	Adrenal hormone preparations	Dexamethasone Palmitate	4	0.1	3	75.0
2454404	Adrenal hormone preparations	Betamethasone Sodium Phosphate	3	0.0	2	66.7
2454405	Adrenal hormone preparations	Dexamethasone Sodium Phosphate	3	0.0	3	100.0
2452002	Adrenal hormone preparations	Hydrocortisone	1	0.0	1	100.0
2454004	Adrenal hormone preparations	Betamethasone	1	0.0	1	100.0
313	Vitamin B preparations (except Vitamin B1)	—	214	2.8	199	93.0
3135002	Vitamin B preparations (except Vitamin B1)	Folic acid	140	1.8	130	92.9
3136004	Vitamin B preparations (except Vitamin B1)	Mecobalamin	62	0.8	58	93.5
3133001	Vitamin B preparations (except Vitamin B1)	Pantethine	8	0.1	7	87.5
3134003	Vitamin B preparations (except Vitamin B1)	Pyridoxal Phosphate Hydrate	6	0.1	6	100.0
3131002	Vitamin B preparations (except Vitamin B1)	Riboflavin Butyrate	2	0.0	2	100.0
3136403	Vitamin B preparations (except Vitamin B1)	Mecobalamin	2	0.0	2	100.0
3131	Vitamin B preparations (except Vitamin B1)	Vitamin B2 preparations	1	0.0	1	100.0
3133	Vitamin B preparations (except Vitamin B1)	Pantothenic acid preparations	1	0.0	1	100.0
264	Analgesics, anti-itchings, astringents, anti-inflammatory agents	—	207	2.7	187	90.3
2649735	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Loxoprofen Sodium Hydrate	92	1.2	84	91.3
2649729	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Ketoprofen	39	0.5	34	87.2
2646730	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Betamethasone Butyrate Propionate	18	0.2	14	77.8
2649799	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Diclofenac Sodium	15	0.2	14	93.3
2649896	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Eslurbiprofen/Mentha oil	10	0.1	9	90.0
2646725	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Difluprednate	7	0.1	6	85.7
2649731	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Felbinac	7	0.1	7	100.0
2646713	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Chloretasol Prorionate	6	0.1	6	100.0
2646717	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Hydrocortisone Butyrate	6	0.1	6	100.0
2646726	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Dexamethasone Propionate	5	0.1	5	100.0
2649722	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Crotamiton	5	0.1	4	80.0
2646708	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Fluocinonide	4	0.1	4	100.0
2646720	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Prednisolone Valerate Acetate	4	0.1	4	100.0
2646731	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Mometasone Furoate	4	0.1	3	75.0
2646723	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Diflorasone Diacetate	3	0.0	3	100.0
2649716	Analgesics, anti-itchings, astringents, anti-inflammatory agents	1,4-dimethyl-7-isopropylazulene	3	0.0	3	100.0
2646700	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Diflucortolone Valerate	2	0.0	2	100.0
2646724	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Dexamethasone Valerate	2	0.0	2	100.0
2646729	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Deprodone Propionate	2	0.0	1	50.0
2647709	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Betamethasone Valerate/Gentamicin Sulfate	2	0.0	2	100.0
2649710	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Zinc Oxide	2	0.0	2	100.0
2649719	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Indometacin	2	0.0	2	100.0
2642702	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Diphenhydramine	1	0.0	1	100.0
2646701	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Betamethasone Valerate	1	0.0	1	100.0
2646709	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Fluocinolone Acetonide	1	0.0	1	100.0
2646711	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Fludrocortide	1	0.0	1	100.0
2647705	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Oxytetracycline Hydrochloride/Hydrocortisone	1	0.0	1	100.0
2649732	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Flurbiprofen	1	0.0	1	100.0
2649800	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Hydrocortisone/Crotamiton	1	0.0	1	100.0
2649801	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Dexamethasone/Drv distillation tar of defattina soybean	1	0.0	1	100.0
2649858	Analgesics, anti-itchings, astringents, anti-inflammatory agents	Methyl Salicylate/Glycyrrhetic Acid Combination	1	0.0	1	100.0
520	Traditional Chinese medicines	—	200	2.6	187	93.5
5200067	Traditional Chinese medicines	Shakukavakanzoto	31	0.4	26	83.9
5200092	Traditional Chinese medicines	Daijenchuto	21	0.3	20	95.2
5200013	Traditional Chinese medicines	Kakkonto	15	0.2	14	93.3
5200017	Traditional Chinese medicines	Kamishoyosan	13	0.2	13	100.0
5200131	Traditional Chinese medicines	Hochuekkito	13	0.2	13	100.0
5200141	Traditional Chinese medicines	Rikkunshito	10	0.1	9	90.0
5200025	Traditional Chinese medicines	Goshajinkigan	9	0.1	9	100.0
5200130	Traditional Chinese medicines	Bofutsushosan	9	0.1	9	100.0
5200038	Traditional Chinese medicines	Keishibukuryogan	8	0.1	8	100.0
5200048	Traditional Chinese medicines	Goreisan	8	0.1	8	100.0
5200129	Traditional Chinese medicines	Boiogito	7	0.1	6	85.7
5200119	Traditional Chinese medicines	Bakumondoto	6	0.1	6	100.0
5200121	Traditional Chinese medicines	Hachimijogan	6	0.1	6	100.0
5200122	Traditional Chinese medicines	Hangekobokuto	6	0.1	6	100.0
5200139	Traditional Chinese medicines	Yokukansan	6	0.1	3	50.0
5200034	Traditional Chinese medicines	Keishikajutsuto	4	0.1	4	100.0
5200039	Traditional Chinese medicines	Keishibukuryogankayokuinin	4	0.1	4	100.0
5200075	Traditional Chinese medicines	Shoseiryuto	4	0.1	4	100.0
5200090	Traditional Chinese medicines	Daiokanzoto	4	0.1	4	100.0
5200113	Traditional Chinese medicines	Nijutsuto	4	0.1	4	100.0
5200054	Traditional Chinese medicines	Saibokuto	3	0.0	3	100.0
5200070	Traditional Chinese medicines	Jumhaidokuto	3	0.0	2	66.7
5200089	Traditional Chinese medicines	Sokeikaketsuto	3	0.0	3	100.0
5200136	Traditional Chinese medicines	Mashimigan	3	0.0	2	66.7
520	Traditional Chinese medicines	Traditional Chinese medicines	2	0.0	2	100.0
5200005	Traditional Chinese medicines	Unkeito	2	0.0	2	100.0
5200007	Traditional Chinese medicines	Epikajutsuto	2	0.0	2	100.0
5200015	Traditional Chinese medicines	Kakkontokasenkyushin'i	2	0.0	2	100.0
5200046	Traditional Chinese medicines	Goshuyuto	2	0.0	2	100.0
5200055	Traditional Chinese medicines	Saireito	2	0.0	2	100.0
5200056	Traditional Chinese medicines	Sansonito	2	0.0	2	100.0
5200071	Traditional Chinese medicines	Junchoto	2	0.0	2	100.0
5200072	Traditional Chinese medicines	Shokenchuto	2	0.0	2	100.0
5200117	Traditional Chinese medicines	Niininyoito	2	0.0	1	50.0
5200127	Traditional Chinese medicines	Bukuryoigohangekobokuto	2	0.0	2	100.0
5200133	Traditional Chinese medicines	Maobushisashinto	2	0.0	2	100.0
5200145	Traditional Chinese medicines	Ryokeijutsukanto	2	0.0	2	100.0
5200006	Traditional Chinese medicines	Unsejin	1	0.0	1	100.0
5200010	Traditional Chinese medicines	Orento	1	0.0	1	100.0
5200019	Traditional Chinese medicines	Kambakutaisoto	1	0.0	1	100.0
5200026	Traditional Chinese medicines	Kumbinroto	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
5200027	Traditional Chinese medicines	Keigairengyoto	1	0.0	1	100.0
5200043	Traditional Chinese medicines	Kososan	1	0.0	1	100.0
5200044	Traditional Chinese medicines	Gokoto	1	0.0	1	100.0
5200045	Traditional Chinese medicines	Goshakusan	1	0.0	1	100.0
5200050	Traditional Chinese medicines	Saikokaryukotsuboreito	1	0.0	1	100.0
5200051	Traditional Chinese medicines	Saikokeishito	1	0.0	1	100.0
5200052	Traditional Chinese medicines	Saikokeishikankyoto	1	0.0	1	100.0
5200069	Traditional Chinese medicines	Juzentaihoto	1	0.0	1	100.0
5200074	Traditional Chinese medicines	Shosaikotokakikyosekko	1	0.0	1	100.0
5200080	Traditional Chinese medicines	Shin'iseihaito	1	0.0	1	100.0
5200094	Traditional Chinese medicines	Daisaikotokyodaio	1	0.0	1	100.0
5200095	Traditional Chinese medicines	Daijokito	1	0.0	1	100.0
5200098	Traditional Chinese medicines	Jidabokuppo	1	0.0	1	100.0
5200103	Traditional Chinese medicines	Choreito	1	0.0	1	100.0
5200106	Traditional Chinese medicines	Tokakujokito	1	0.0	1	100.0
5200107	Traditional Chinese medicines	Tokito	1	0.0	1	100.0
5200110	Traditional Chinese medicines	Tokishigyakukagoshuyushokyo	1	0.0	1	100.0
5200111	Traditional Chinese medicines	Tokishakuyakusan	1	0.0	1	100.0
5200120	Traditional Chinese medicines	Hachimigan	1	0.0	1	100.0
5200124	Traditional Chinese medicines	Hangebakujutsutemmato	1	0.0	1	100.0
5200134	Traditional Chinese medicines	Makyokansekitto	1	0.0	1	100.0
5200135	Traditional Chinese medicines	Makyovokukanto	1	0.0	1	100.0
5200138	Traditional Chinese medicines	Yokuininto	1	0.0	1	100.0
5200140	Traditional Chinese medicines	Yokukansankachimpihange	1	0.0	1	100.0
5200144	Traditional Chinese medicines	Yokukovutsukanto	1	0.0	1	100.0
5200146	Traditional Chinese medicines	Rokumigan	1	0.0	1	100.0
5200148	Traditional Chinese medicines	Bushirichuto	1	0.0	1	100.0
119	Agents affecting central nervous system-Miscellaneous	—	189	2.5	167	88.4
1190017	Agents affecting central nervous system-Miscellaneous	Pregabalin	75	1.0	67	89.3
1190026	Agents affecting central nervous system-Miscellaneous	Mirogabalin Besilate	37	0.5	33	89.2
1190023	Agents affecting central nervous system-Miscellaneous	Suvorexant	31	0.4	26	83.9
1190027	Agents affecting central nervous system-Miscellaneous	Lenvorexant	26	0.3	25	96.2
1190012	Agents affecting central nervous system-Miscellaneous	Donepezil Hydrochloride	9	0.1	7	77.8
1190016	Agents affecting central nervous system-Miscellaneous	Ramelteon	7	0.1	4	57.1
1190018	Agents affecting central nervous system-Miscellaneous	Memantine Hydrochloride	4	0.1	3	75.0
1190004	Agents affecting central nervous system-Miscellaneous	Tiapride Hydrochloride	2	0.0	2	100.0
1190019	Agents affecting central nervous system-Miscellaneous	Galantamine Hydrobromide	2	0.0	1	50.0
1190044	Agents affecting central nervous system-Miscellaneous	Galcanzumab (Genetical Recombination)	2	0.0	2	100.0
1190014	Agents affecting central nervous system-Miscellaneous	Taltirelin Hydrate	1	0.0	1	100.0
1190015	Agents affecting central nervous system-Miscellaneous	Nalfurafine Hydrochloride	1	0.0	1	100.0
394	Gout preparations	—	188	2.4	166	88.3
3949003	Gout preparations	Febuxostat	114	1.5	103	90.4
3943001	Gout preparations	Allopurinol	39	0.5	33	84.6
3949002	Gout preparations	Benzbromarone	14	0.2	13	92.9
3949101	Gout preparations	Potassium Citrate/Sodium Citrate Hydrate	13	0.2	12	92.3
3949005	Gout preparations	Dotinurad	10	0.1	9	90.0
3949004	Gout preparations	Topiroxostat	7	0.1	5	71.4
3941001	Gout preparations	Colchicine	2	0.0	2	100.0
117	Psychotropics	—	146	1.9	131	89.7
1179025	Psychotropics	Etizolam	55	0.7	49	89.1
1179052	Psychotropics	Duloxetine Hydrochloride	44	0.6	41	93.2
1179012	Psychotropics	Clozapepam	12	0.2	12	100.0
1179003	Psychotropics	Amirtrityline Hydrochloride	8	0.1	8	100.0
1179046	Psychotropics	Serrtraline Hydrochloride	7	0.1	6	85.7
1179051	Psychotropics	Mirtazamine	7	0.1	7	100.0
1179037	Psychotropics	Trazodone Hydrochloride	6	0.1	4	66.7
1179041	Psychotropics	Paroxetine Hydrochloride Hydrate	5	0.1	4	80.0
1179042	Psychotropics	Quetiapine Fumarate	5	0.1	4	80.0
1179017	Psychotropics	Lithium Carbonate	4	0.1	4	100.0
1179054	Psychotropics	Escitalopram Oxalate	4	0.1	3	75.0
1172011	Psychotropics	Prochlorperazine Maleate	2	0.0	2	100.0
1179039	Psychotropics	Fluvoxamine Maleate	2	0.0	1	50.0
1179050	Psychotropics	Atomoxetine Hydrochloride	2	0.0	1	50.0
1171002	Psychotropics	Chlorpromazine Hydrochloride	1	0.0	1	100.0
1172014	Psychotropics	Levomopromazine Maleate	1	0.0	1	100.0
1174006	Psychotropics	Imipramine Hydrochloride	1	0.0	1	100.0
1179005	Psychotropics	Hydroxyzine Hydrochloride	1	0.0	1	100.0
1179009	Psychotropics	Methylphenidate Hydrochloride	1	0.0	1	100.0
1179033	Psychotropics	Mianserin Hydrochloride	1	0.0	1	100.0
1179040	Psychotropics	Milnacipran Hydrochloride	1	0.0	1	100.0
1179045	Psychotropics	Aripiprazole	1	0.0	1	100.0
1179055	Psychotropics	Venlafaxine Hydrochloride	1	0.0	1	100.0
1179057	Psychotropics	Guanfacine Hydrochloride	1	0.0	1	100.0
1179060	Psychotropics	Vortioxetine Hydrobromide	1	0.0	1	100.0
1179061	Psychotropics	Lurasidone Hydrochloride	1	0.0	1	100.0
239	Digestive organ agents-Miscellaneous	—	144	1.9	131	91.0
2399010	Digestive organ agents-Miscellaneous	Mosapride Citrate Hydrate	43	0.6	39	90.7
2399005	Digestive organ agents-Miscellaneous	Domeperdone	27	0.4	26	96.3
2399015	Digestive organ agents-Miscellaneous	Acotamide Hydrochloride Hydrate	13	0.2	13	100.0
2399009	Digestive organ agents-Miscellaneous	Mesalazine	10	0.1	10	100.0
2399017	Digestive organ agents-Miscellaneous	Linacotide	10	0.1	9	90.0
2399004	Digestive organ agents-Miscellaneous	Metoclopramide	9	0.1	8	88.9
2399014	Digestive organ agents-Miscellaneous	Ramosteron Hydrochloride	9	0.1	6	66.7
2399006	Digestive organ agents-Miscellaneous	Trimebutine Maleate	6	0.1	6	100.0
2399011	Digestive organ agents-Miscellaneous	Polycarbophil Calcium	6	0.1	6	100.0
2399499	Digestive organ agents-Miscellaneous	Infliximab (Genetical Recombination)	5	0.1	2	40.0
2391404	Digestive organ agents-Miscellaneous	Palonosetron Hydrochloride	3	0.0	3	100.0
2399012	Digestive organ agents-Miscellaneous	Cevimeline Hydrochloride Hydrate	3	0.0	3	100.0
2399013	Digestive organ agents-Miscellaneous	Pilocarpine Hydrochloride	3	0.0	3	100.0
2391008	Digestive organ agents-Miscellaneous	Aprepitant	2	0.0	2	100.0
2399706	Digestive organ agents-Miscellaneous	Dexamethasone	2	0.0	2	100.0
2391400	Digestive organ agents-Miscellaneous	Granisetron Hydrochloride	1	0.0	1	100.0
2391406	Digestive organ agents-Miscellaneous	Fosnetupitant Chloride Hydrochloride	1	0.0	1	100.0
2399401	Digestive organ agents-Miscellaneous	Metoclopramide Hydrochloride	1	0.0	1	100.0
2399707	Digestive organ agents-Miscellaneous	Triamcinolone Acetonide	1	0.0	1	100.0
2399710	Digestive organ agents-Miscellaneous	Dequalinium Chloride	1	0.0	1	100.0
2399713	Digestive organ agents-Miscellaneous	Sodium Guafenate Hydrate	1	0.0	1	100.0
2399716	Digestive organ agents-Miscellaneous	Budesonide	1	0.0	1	100.0
2399801	Digestive organ agents-Miscellaneous	Dipotassium Phosphate/Inorganic Salts Combination	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
229	Respiratory organ agents-Miscellaneous	—	140	1.8	135	96.4
2290802	Respiratory organ agents-Miscellaneous	Fluticasone Propionate/Formoterol Fumarate Hydrate	31	0.4	31	100.0
2290804	Respiratory organ agents-Miscellaneous	Fluticasone Furoate/Umeclidinium Bromide/Vilanterol Trifluoromethanesulfonate	31	0.4	29	93.5
2290801	Respiratory organ agents-Miscellaneous	Budesonide/Formoterol Fumarate Hydrate	27	0.4	24	88.9
2290803	Respiratory organ agents-Miscellaneous	Vilanterol Trifluoromethanesulfonate/Fluticasone Furoate	18	0.2	18	100.0
2290800	Respiratory organ agents-Miscellaneous	Salmeterol Xinafoate/Fluticasone Propionate	11	0.1	11	100.0
2290701	Respiratory organ agents-Miscellaneous	Budesonide	4	0.1	4	100.0
2290702	Respiratory organ agents-Miscellaneous	Ciclesonide	4	0.1	4	100.0
2290807	Respiratory organ agents-Miscellaneous	Indacaterol Acetate/Glycopyrronium Bromide/Mometasone Furoate	4	0.1	4	100.0
2290805	Respiratory organ agents-Miscellaneous	Budesonide/Glycopyrronium Bromide/Formoterol Fumarate Hydrate	3	0.0	3	100.0
2290402	Respiratory organ agents-Miscellaneous	Benralizumab (Genetical Recombination)	2	0.0	2	100.0
2290700	Respiratory organ agents-Miscellaneous	Fluticasone Propionate	2	0.0	2	100.0
2290703	Respiratory organ agents-Miscellaneous	Mometasone Furoate	2	0.0	2	100.0
2290705	Respiratory organ agents-Miscellaneous	Fluticasone Furoate	2	0.0	2	100.0
2290400	Respiratory organ agents-Miscellaneous	Omalizumab (Genetical Recombination)	1	0.0	1	100.0
259	Urogenital and anal organ agents-Miscellaneous	—	140	1.8	115	82.1
2590017	Urogenital and anal organ agents-Miscellaneous	Vibegron	35	0.5	28	80.0
2590010	Urogenital and anal organ agents-Miscellaneous	Sildenafil	28	0.4	26	92.9
2590014	Urogenital and anal organ agents-Miscellaneous	Mirabegron	28	0.4	24	85.7
2590008	Urogenital and anal organ agents-Miscellaneous	Tamsulosin Hydrochloride	22	0.3	16	72.7
2590093	Urogenital and anal organ agents-Miscellaneous	Tadalafil	18	0.2	15	83.3
2590009	Urogenital and anal organ agents-Miscellaneous	Naftopidil	14	0.2	13	92.9
2590011	Urogenital and anal organ agents-Miscellaneous	Sildenafil Succinate	13	0.2	11	84.6
2590013	Urogenital and anal organ agents-Miscellaneous	Imidafenacin	7	0.1	7	100.0
2590015	Urogenital and anal organ agents-Miscellaneous	Fesoterodine Fumarate	3	0.0	3	100.0
2590003	Urogenital and anal organ agents-Miscellaneous	Ceritin Pollen Extract	2	0.0	2	100.0
2590007	Urogenital and anal organ agents-Miscellaneous	Propiverine Hydrochloride	2	0.0	1	50.0
2590100	Urogenital and anal organ agents-Miscellaneous	Chimaphila Populus Extract Combination	2	0.0	2	100.0
2590002	Urogenital and anal organ agents-Miscellaneous	Flavoxate Hydrochloride	1	0.0	1	100.0
212	Antiarrhythmic agents	—	137	1.8	117	85.4
2123016	Antiarrhythmic agents	Bisoprolol Fumarate	88	1.1	76	86.4
2123011	Antiarrhythmic agents	Atenolol	21	0.3	19	90.5
2129009	Antiarrhythmic agents	Flecainide Acetate	7	0.1	6	85.7
2129008	Antiarrhythmic agents	Pilsicainide Hydrochloride Hydrate	6	0.1	3	50.0
2129011	Antiarrhythmic agents	Bepiridil Hydrochloride Hydrate	5	0.1	5	100.0
2123014	Antiarrhythmic agents	Arrotinolol Hydrochloride	3	0.0	3	100.0
2129002	Antiarrhythmic agents	Disopyramide	3	0.0	1	33.3
2123008	Antiarrhythmic agents	Propranolol Hydrochloride	2	0.0	2	100.0
2129003	Antiarrhythmic agents	Mexiletine Hydrochloride	2	0.0	2	100.0
2129007	Antiarrhythmic agents	Cibenzoline Succinate	2	0.0	2	100.0
2129010	Antiarrhythmic agents	Amiodarone Hydrochloride	2	0.0	2	100.0
2121002	Antiarrhythmic agents	Procainamide Hydrochloride	1	0.0	0	0.0
2129004	Antiarrhythmic agents	Aprindine Hydrochloride	1	0.0	1	100.0
234	Antacids	—	133	1.7	125	94.0
2344002	Antacids	Magnesium Oxide	127	1.6	119	93.7
2349100	Antacids	Aluminum Hydroxide Gel/Magnesium Hydroxide	2	0.0	2	100.0
2349101	Antacids	Dried Aluminum Hydroxide Gel/Magnesium Hydroxide	2	0.0	2	100.0
2343006	Antacids	Synthetic Hydrated Alumina	1	0.0	1	100.0
2344005	Antacids	Sodium Bicarbonate	1	0.0	1	100.0
333	Anticoagulants	—	126	1.6	106	84.1
3339950	Anticoagulants	Heparinoid	39	0.5	35	89.7
3339002	Anticoagulants	Edoxaban Tosilate Hydrate	31	0.4	28	90.3
3332001	Anticoagulants	Warfarin Potassium	18	0.2	16	88.9
3339004	Anticoagulants	Apixaban	18	0.2	12	66.7
3339003	Anticoagulants	Rivaroxaban	16	0.2	11	68.8
3339001	Anticoagulants	Dabigatran Etxilate Methanesulfonate	4	0.1	4	100.0
333	Anticoagulants	Anticoagulants	1	0.0	1	100.0
249	Hormones-Miscellaneous	—	112	1.5	91	81.3
2492419	Hormones-Miscellaneous	Insulin Degludec (Genetical Recombination)	20	0.3	19	95.0
2499011	Hormones-Miscellaneous	Dutasteride	20	0.3	18	90.0
2499014	Hormones-Miscellaneous	Semaglutide (Genetical Recombination)	20	0.3	17	85.0
2492415	Hormones-Miscellaneous	Insulin Aspart (Genetical Recombination)	13	0.2	12	92.3
2492414	Hormones-Miscellaneous	Insulin Lispro (Genetical Recombination)	9	0.1	6	66.7
2499416	Hormones-Miscellaneous	Dulaglutide (Genetical Recombination)	9	0.1	8	88.9
2491001	Hormones-Miscellaneous	Kallidinogenase	8	0.1	7	87.5
2492500	Hormones-Miscellaneous	Insulin Degludec (Genetical Recombination)/Insulin Aspart (Genetical Recombination) Combination	8	0.1	4	50.0
2492416	Hormones-Miscellaneous	Insulin Glargine (Genetical Recombination)	5	0.1	4	80.0
2492420	Hormones-Miscellaneous	Insulin Glargine (Genetical Recombination) [Biosimilar 1]	5	0.1	2	40.0
2499418	Hormones-Miscellaneous	Semaglutide (Genetical Recombination)	5	0.1	1	20.0
2499010	Hormones-Miscellaneous	Dienogest	3	0.0	3	100.0
2499410	Hormones-Miscellaneous	Liraglutide (Genetical Recombination)	3	0.0	3	100.0
2492406	Hormones-Miscellaneous	Insulin	2	0.0	2	100.0
2492417	Hormones-Miscellaneous	Insulin Detemir (Genetical Recombination)	2	0.0	2	100.0
2492422	Hormones-Miscellaneous	Insulin Lispro (Genetical Recombination) [Biosimilar 1]	2	0.0	2	100.0
2499013	Hormones-Miscellaneous	Relugolix	2	0.0	2	100.0
2499091	Hormones-Miscellaneous	Finasteride	2	0.0	1	50.0
2492413	Hormones-Miscellaneous	Insulin Human (Genetical Recombination)	1	0.0	1	100.0
2499407	Hormones-Miscellaneous	Leuporelin Acetate	1	0.0	1	100.0
2499422	Hormones-Miscellaneous	Tirzepatide	1	0.0	0	0.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
243	Thyroid and parathyroid hormone preparations	—	110	1.4	94	85.5
2431004	Thyroid and parathyroid hormone preparations	Levothyroxine Sodium Hydrate	43	0.6	38	88.4
2431001	Thyroid and parathyroid hormone preparations	Dried Thyroid	38	0.5	33	86.8
2432001	Thyroid and parathyroid hormone preparations	Thiamazole	15	0.2	11	73.3
2439401	Thyroid and parathyroid hormone preparations	Teriparatide Acetate	6	0.1	5	83.3
2432002	Thyroid and parathyroid hormone preparations	Propylthiouracil	4	0.1	3	75.0
2439400	Thyroid and parathyroid hormone preparations	Teriparatide (Genetical Recombination)	4	0.1	4	100.0
231	Antidiarrheals, intestinal regulators	—	108	1.4	98	90.7
2316009	Antidiarrheals, intestinal regulators	Clostridium Butyricum Preparation	46	0.6	42	91.3
2316012	Antidiarrheals, intestinal regulators	Lactomin	16	0.2	14	87.5
2316017	Antidiarrheals, intestinal regulators	Clostridium Butyricum Combination	16	0.2	16	100.0
2316014	Antidiarrheals, intestinal regulators	Bifidobacterium Formulation (4)	12	0.2	11	91.7
2316020	Antidiarrheals, intestinal regulators	Bifidobacterium Formulation (5)	8	0.1	6	75.0
2316004	Antidiarrheals, intestinal regulators	Antibiotics-Resistant Lactic Acid Bacteriae Formulation (3)	5	0.1	5	100.0
2319001	Antidiarrheals, intestinal regulators	Loperamide Hydrochloride	5	0.1	4	80.0
2318001	Antidiarrheals, intestinal regulators	Dimethicone	4	0.1	4	100.0
2319100	Antidiarrheals, intestinal regulators	Berberine Chloride Hydrate/Berberine Chloride Hydrate	3	0.0	2	66.7
231	Antidiarrheals, intestinal regulators	Antidiarrheals, intestinal regulators	1	0.0	1	100.0
621	Sulfonamides	—	87	1.1	79	90.8
6219001	Sulfonamides	Salazosulfapyridine	87	1.1	79	90.8
223	Expectorants	—	78	1.0	73	93.6
2233002	Expectorants	L-Carbocisteine	47	0.6	45	95.7
2239001	Expectorants	Ambroxol Hydrochloride	35	0.5	33	94.3
2233004	Expectorants	Fudosteine	5	0.1	4	80.0
219	Cardiovascular agents-Miscellaneous	—	76	1.0	63	82.9
2190006	Cardiovascular agents-Miscellaneous	Tocopherol Nicotinate	23	0.3	20	87.0
2190041	Cardiovascular agents-Miscellaneous	Sacubitril Valsartan Sodium Hydrate	14	0.2	10	71.4
2190101	Cardiovascular agents-Miscellaneous	Amlodipine besilate/Atorvastatin Calcium Hydrate Combination (1)	10	0.1	8	80.0
2190023	Cardiovascular agents-Miscellaneous	Lomerizine Hydrochloride	8	0.1	8	100.0
2190016	Cardiovascular agents-Miscellaneous	Calcium Polystyrene Sulfonate	7	0.1	6	85.7
2190103	Cardiovascular agents-Miscellaneous	Amlodipine besilate/Atorvastatin Calcium Hydrate Combination (3)	3	0.0	3	100.0
2190005	Cardiovascular agents-Miscellaneous	Heniprodil Tartrate	2	0.0	1	50.0
2190022	Cardiovascular agents-Miscellaneous	Amezinium Methylsulfate	2	0.0	1	50.0
2190024	Cardiovascular agents-Miscellaneous	Precipitated Calcium Carbonate	2	0.0	1	50.0
2190029	Cardiovascular agents-Miscellaneous	Lanthanum Carbonate Hydrate	2	0.0	2	100.0
2190037	Cardiovascular agents-Miscellaneous	Selexipag	2	0.0	2	100.0
2190104	Cardiovascular agents-Miscellaneous	Amlodipine besilate/Atorvastatin Calcium Hydrate Combination (4)	2	0.0	2	100.0
2190021	Cardiovascular agents-Miscellaneous	Nicergoline	1	0.0	1	100.0
2190030	Cardiovascular agents-Miscellaneous	Tadalafil	1	0.0	1	100.0
2190032	Cardiovascular agents-Miscellaneous	Bixalomer	1	0.0	1	100.0
2190033	Cardiovascular agents-Miscellaneous	Ferrie Citrate Hydrate	1	0.0	1	100.0
2190034	Cardiovascular agents-Miscellaneous	Riociguat	1	0.0	1	100.0
2190035	Cardiovascular agents-Miscellaneous	Macitentan	1	0.0	1	100.0
2190044	Cardiovascular agents-Miscellaneous	Finerenone	1	0.0	1	100.0
213	Diuretics	—	74	1.0	60	81.1
2139005	Diuretics	Furosemide	25	0.3	21	84.0
2132003	Diuretics	Trichlormethiazide	23	0.3	20	87.0
2133001	Diuretics	Spironolactone	11	0.1	9	81.8
2139008	Diuretics	Azosemide	11	0.1	10	90.9
2139001	Diuretics	Isosorbide	3	0.0	3	100.0
2139009	Diuretics	Torsemide	3	0.0	1	33.3
2132004	Diuretics	Hydrochlorothiazide	1	0.0	0	0.0
2132006	Diuretics	Benzylhydrochlorothiazide	1	0.0	0	0.0
2139011	Diuretics	Tolvaptan	1	0.0	0	0.0
236	Cholagogues	—	68	0.9	60	88.2
2362001	Cholagogues	Ursodeoxycholic Acid	68	0.9	60	88.2
235	Purgatives, clysters	—	66	0.9	61	92.4
2354003	Purgatives, clysters	Sennoside	25	0.3	24	96.0
2359006	Purgatives, clysters	Lubiprostone	14	0.2	12	85.7
2359102	Purgatives, clysters	Senna Leaf/Fruit	10	0.1	9	90.0
2359005	Purgatives, clysters	Sodium Picosulfate Hydrate	8	0.1	8	100.0
2359008	Purgatives, clysters	Ellobixibat Hydrate	8	0.1	8	100.0
2359110	Purgatives, clysters	Macrogel 4000/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	6	0.1	6	100.0
2354002	Purgatives, clysters	Senna Extract	2	0.0	1	50.0
2359103	Purgatives, clysters	Rhubarb/Senna Combination	2	0.0	2	100.0
2357701	Purgatives, clysters	Glycerin	1	0.0	1	100.0
2359007	Purgatives, clysters	Naldemedine Tosilate	1	0.0	1	100.0
2359800	Purgatives, clysters	Sodium Bicarbonate/Anhydrous Sodium Dihydrogen Phosphate	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
131	Ophthalmic agents	—	58	0.8	56	96.6
1319720	Ophthalmic agents	Purified sodium hyaluronate	13	0.2	13	100.0
1319752	Ophthalmic agents	Olanpatadine Hydrochloride	10	0.1	9	90.0
1319762	Ophthalmic agents	Emastinate Hydrochloride	10	0.1	10	100.0
1319758	Ophthalmic agents	Diquafosol Sodium	9	0.1	9	100.0
1315704	Ophthalmic agents	Fluorometholone	4	0.1	4	100.0
1315706	Ophthalmic agents	Betamethasone Sodium Phosphate	3	0.0	3	100.0
1319706	Ophthalmic agents	Prenoxine	3	0.0	3	100.0
1319730	Ophthalmic agents	Ketotifen Fumarate	3	0.0	2	66.7
1319739	Ophthalmic agents	Latanoprost	3	0.0	3	100.0
1319701	Ophthalmic agents	Carteolol Hydrochloride	2	0.0	2	100.0
1319702	Ophthalmic agents	Timolol Maleate	2	0.0	2	100.0
1319722	Ophthalmic agents	Ofloxacin	2	0.0	2	100.0
1319742	Ophthalmic agents	Levofloxacin Hydrate	2	0.0	2	100.0
1319756	Ophthalmic agents	Tafuprost	2	0.0	2	100.0
1319757	Ophthalmic agents	Binatoprost	2	0.0	2	100.0
1319764	Ophthalmic agents	Omideneap Isopropyl	2	0.0	2	100.0
1319819	Ophthalmic agents	Dorzolamide Hydrochloride/Timolol Maleate	2	0.0	2	100.0
1319821	Ophthalmic agents	Brinzolamide/Timolol Maleate	2	0.0	2	100.0
1317710	Ophthalmic agents	Dibekacin Sulfate	1	0.0	1	100.0
1319710	Ophthalmic agents	Cyanocobalamin	1	0.0	1	100.0
1319724	Ophthalmic agents	Pranoprofen	1	0.0	1	100.0
1319743	Ophthalmic agents	Bromfenac Sodium Hydrate	1	0.0	1	100.0
1319746	Ophthalmic agents	Levocabastine Hydrochloride	1	0.0	1	100.0
1319748	Ophthalmic agents	Brinzolamide	1	0.0	1	100.0
1319749	Ophthalmic agents	Gatifloxacin Hydrate	1	0.0	1	100.0
1319754	Ophthalmic agents	Travoprost	1	0.0	1	100.0
1319760	Ophthalmic agents	Rebanipide	1	0.0	1	100.0
1319763	Ophthalmic agents	Ripasudil Hydrochloride Hydrate	1	0.0	1	100.0
1319807	Ophthalmic agents	Fradiomycin Sulfate/methylprednisolone	1	0.0	1	100.0
1319808	Ophthalmic agents	Boric acid-inorganic salts combination	1	0.0	1	100.0
1319820	Ophthalmic agents	Travoprost/Timolol Maleate	1	0.0	1	100.0
1319823	Ophthalmic agents	Carteolol Hydrochloride/Latanoprost	1	0.0	1	100.0
1319825	Ophthalmic agents	Brimonidine Tartrate/Brinzolamide	1	0.0	1	100.0
629	Chemotherapeutics-Miscellaneous	—	54	0.7	48	88.9
6290100	Chemotherapeutics-Miscellaneous	Sulfamethoxazole/Trimethoprim	34	0.4	31	91.2
6290007	Chemotherapeutics-Miscellaneous	Fosravuconazole L-Lysine Ethanolate	5	0.1	4	80.0
6290702	Chemotherapeutics-Miscellaneous	Efinacozole	5	0.1	4	80.0
6290004	Chemotherapeutics-Miscellaneous	Itraconazole	3	0.0	3	100.0
6290005	Chemotherapeutics-Miscellaneous	Terbinafine Hydrochloride	3	0.0	2	66.7
6290703	Chemotherapeutics-Miscellaneous	Luliconazole	3	0.0	3	100.0
6290006	Chemotherapeutics-Miscellaneous	Atovaquone	2	0.0	2	100.0
429	Antineoplastics-Miscellaneous	—	50	0.6	45	90.0
4291010	Antineoplastics-Miscellaneous	Anastrozole	11	0.1	9	81.8
4291003	Antineoplastics-Miscellaneous	Tamoxifen Citrate	7	0.1	7	100.0
4291015	Antineoplastics-Miscellaneous	Letrozole	4	0.1	4	100.0
4291009	Antineoplastics-Miscellaneous	Bicalutamide	3	0.0	1	33.3
4291045	Antineoplastics-Miscellaneous	Osimertinib Mesilate	3	0.0	2	66.7
4291049	Antineoplastics-Miscellaneous	Ixazomib Citrate	3	0.0	3	100.0
4291403	Antineoplastics-Miscellaneous	Carboplatin	3	0.0	3	100.0
4291021	Antineoplastics-Miscellaneous	Nilotinib Hydrochloride Hydrate	2	0.0	2	100.0
4291024	Antineoplastics-Miscellaneous	Lenalidomide Hydrate	2	0.0	2	100.0
4291039	Antineoplastics-Miscellaneous	Lenvatinib Mesilate	2	0.0	2	100.0
4291413	Antineoplastics-Miscellaneous	Bevacizumab (Genetical Recombination)	2	0.0	2	100.0
4291454	Antineoplastics-Miscellaneous	Iatuximab (Genetical Recombination)	2	0.0	2	100.0
4291007	Antineoplastics-Miscellaneous	Toremifene Citrate	1	0.0	1	100.0
4291011	Antineoplastics-Miscellaneous	Imatinib Mesilate	1	0.0	1	100.0
4291016	Antineoplastics-Miscellaneous	Erlotinib Hydrochloride	1	0.0	1	100.0
4291020	Antineoplastics-Miscellaneous	Dasatinib Hydrate	1	0.0	1	100.0
4291034	Antineoplastics-Miscellaneous	Ruxolitinib Phosphate	1	0.0	1	100.0
4291035	Antineoplastics-Miscellaneous	Sirolimus	1	0.0	1	100.0
4291043	Antineoplastics-Miscellaneous	Ibrutinib	1	0.0	1	100.0
4291076	Antineoplastics-Miscellaneous	Sotorasib	1	0.0	1	100.0
4291441	Antineoplastics-Miscellaneous	Atezolizumab (Genetical Recombination)	1	0.0	1	100.0
4291443	Antineoplastics-Miscellaneous	Durvalumab (Genetical Recombination)	1	0.0	1	100.0
4291500	Antineoplastics-Miscellaneous	Daratumumab (Genetical Recombination)/Vorhialuronidase Alfa (Genetical Recombination)	1	0.0	1	100.0
317	Multivitamin preparations	—	41	0.5	38	92.7
3179115	Multivitamin preparations	Ascorbic Acid/Calcium Pantothenate (1)	26	0.3	24	92.3
3179108	Multivitamin preparations	Benfotiamine/B6/B12 Combination (1)	7	0.1	6	85.7
3179106	Multivitamin preparations	Octotiamine/B2/B6/B12 Combination	5	0.1	5	100.0
3179121	Multivitamin preparations	Retinol/Calciferol Combination	4	0.1	4	100.0
3179100	Multivitamin preparations	Riboflavin/Pyridoxine Hydrochloride	1	0.0	1	100.0
113	Antiepileptics	—	40	0.5	34	85.0
1139003	Antiepileptics	Clonazepam	14	0.2	12	85.7
1139004	Antiepileptics	Sodium Valproate	14	0.2	11	78.6
1139002	Antiepileptics	Carbamazepine	5	0.1	5	100.0
1139010	Antiepileptics	Levetiracetam	4	0.1	3	75.0
1139009	Antiepileptics	Lamotrigine	3	0.0	3	100.0
1139008	Antiepileptics	Topiramate	2	0.0	1	50.0
1132002	Antiepileptics	Phenytoin	1	0.0	1	100.0
1139005	Antiepileptics	Zonisamide	1	0.0	1	100.0
1139007	Antiepileptics	Gabapentin	1	0.0	1	100.0
1139015	Antiepileptics	Lacosamide	1	0.0	1	100.0
322	Mineral preparations	—	40	0.5	37	92.5
3222013	Mineral preparations	Sodium Ferrous Citrate	26	0.3	25	96.2
3229005	Mineral preparations	Potassium L-Aspartate	6	0.1	4	66.7
3221002	Mineral preparations	Potassium Iodide	2	0.0	2	100.0
3222007	Mineral preparations	Dried Ferrous Sulfate (3)	2	0.0	2	100.0
3222010	Mineral preparations	Ferrous Fumarate	2	0.0	1	50.0
3229002	Mineral preparations	Potassium Chloride	2	0.0	2	100.0
3222012	Mineral preparations	Ferrie Pyrophosphate, Soluble	1	0.0	1	100.0
3222400	Mineral preparations	Ferrie Oxide, Saccharated	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
321	Calcium preparations	—	39	0.5	36	92.3
3219100	Calcium preparations	Precipitated Calcium Carbonate/Cholecalciferol/Magnesium Carbonate	29	0.4	27	93.1
3214001	Calcium preparations	Calcium L-Aspartate Hydrate	10	0.1	9	90.0
639	Biological preparations-Miscellaneous	—	39	0.5	36	92.3
6399421	Biological preparations-Miscellaneous	Tocilizumab (Genetical Recombination)	39	0.5	36	92.3
225	Bronchodilators	—	36	0.5	34	94.4
2251001	Bronchodilators	Theophylline	15	0.2	15	100.0
2259707	Bronchodilators	Tulobuterol	5	0.1	5	100.0
2259709	Bronchodilators	Tiotropium Bromide Hydrate	5	0.1	3	60.0
2259806	Bronchodilators	Umeclidinium Bromide/Vilanterol Trifenatate	4	0.1	4	100.0
2259807	Bronchodilators	Tiotropium Bromide Hydrate/Olodaterol Hydrochloride	3	0.0	3	100.0
2259703	Bronchodilators	Beclomethasone Dipropionate	2	0.0	2	100.0
2259004	Bronchodilators	Procaterol Hydrochloride Hydrate	1	0.0	1	100.0
2259712	Bronchodilators	Glycopyrronium Bromide	1	0.0	1	100.0
2259714	Bronchodilators	Umeclidinium Bromide	1	0.0	1	100.0
2259805	Bronchodilators	Indacaterol Maleate/Glycopyrronium Bromide	1	0.0	1	100.0
124	Antispasmodics	—	35	0.5	34	97.1
1249009	Antispasmodics	Eperisone Hydrochloride	16	0.2	15	93.8
1249010	Antispasmodics	Tizanidine Hydrochloride	15	0.2	15	100.0
1242002	Antispasmodics	Scopolamine Butylbromide	3	0.0	3	100.0
1249006	Antispasmodics	Baclofen	1	0.0	1	100.0
1249008	Antispasmodics	Aflqualone	1	0.0	1	100.0
132	Otic and nasal agents	—	33	0.4	32	97.0
1329711	Otic and nasal agents	Fluticasone Furoate	15	0.2	15	100.0
1329710	Otic and nasal agents	Mometasone Furoate Hydrate	9	0.1	8	88.9
1329707	Otic and nasal agents	Fluticasone Propionate	6	0.1	6	100.0
1329100	Otic and nasal agents	Nicotinamide/Papaverine Hydrochloride	3	0.0	3	100.0
1329705	Otic and nasal agents	Ketotifen Fumarate	1	0.0	1	100.0
614	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	—	31	0.4	31	100.0
6149003	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	Clarithromycin	22	0.3	22	100.0
6149004	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	Azithromycin Hydrate	5	0.1	5	100.0
6141001	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	Erythromycin Ethylsuccinate	3	0.0	3	100.0
6141002	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	Erythromycin	1	0.0	1	100.0
6149002	Antibiotics-Acting mainly on gram-positive bacteria and mycoplasma	Roxithromycin	1	0.0	1	100.0
442	Stimulation therapy agents	—	29	0.4	27	93.1
4420002	Stimulation therapy agents	Bucillamine	24	0.3	22	91.7
4420001	Stimulation therapy agents	Auranofin	3	0.0	3	100.0
4420402	Stimulation therapy agents	Sodium Aurothiomalate	3	0.0	2	66.7
133	Vertigo agents	—	21	0.3	18	85.7
1339005	Vertigo agents	Betahistine Mesilate	17	0.2	16	94.1
1339002	Vertigo agents	Difenidol Hydrochloride	3	0.0	1	33.3
1339100	Vertigo agents	Diphenhydramine Salicylate/Diprophylline	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
613	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	—	21	0.3	21	100.0
6131001	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Amoxicillin Hydrate	6	0.1	6	100.0
6132015	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Cefditoren Pivoxil	3	0.0	3	100.0
6132016	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Cefcapene Pivoxil Hydrochloride Hydrate	3	0.0	3	100.0
6132002	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Cefalexin	2	0.0	2	100.0
6132013	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Cefdinir	2	0.0	2	100.0
6139100	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Amoxicillin Hydrate/Potassium Clavulanate	2	0.0	2	100.0
6132005	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Cefaclor	1	0.0	1	100.0
6132009	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Cefteram Pivoxil	1	0.0	1	100.0
6132419	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Ceftriaxone Sodium Hydrate	1	0.0	1	100.0
6139400	Antibiotics-Acting mainly on gram-positive and gram-negative bacteria	Meropenem Hydrate	1	0.0	1	100.0
332	Hemostatics	—	20	0.3	20	100.0
3327002	Hemostatics	Tranexamic Acid	18	0.2	18	100.0
3321002	Hemostatics	Carbazochrome Sodium Sulfonate Hydrate	1	0.0	1	100.0
3322001	Hemostatics	Gelatin	1	0.0	1	100.0
222	Antitussives	—	19	0.2	17	89.5
2223001	Antitussives	Dextromethorphan Hydrobromide Hydrate	14	0.2	12	85.7
2229001	Antitussives	Dimemorfan Phosphate	3	0.0	3	100.0
2229100	Antitussives	Antitussives (1)	2	0.0	2	100.0
625	Antivirals	—	18	0.2	17	94.4
6250029	Antivirals	Entecavir Hydrate	4	0.1	3	75.0
6250019	Antivirals	Valaciclovir Hydrochloride	3	0.0	3	100.0
6250031	Antivirals	Famciclovir	3	0.0	3	100.0
6250045	Antivirals	Tenofovir Alafenamide Fumarate	3	0.0	3	100.0
6250700	Antivirals	Vidarabine	3	0.0	3	100.0
6250046	Antivirals	Amenamivir	1	0.0	1	100.0
6250091	Antivirals	Molnupiravir	1	0.0	1	100.0
6250092	Antivirals	Ensitrelvir Fumarate	1	0.0	1	100.0
216	Vasoconstrictors	—	15	0.2	15	100.0
2160006	Vasoconstrictors	Rizatriptan Benzoate	6	0.1	6	100.0
2160004	Vasoconstrictors	Zolmitriptan	3	0.0	3	100.0
2160002	Vasoconstrictors	Midodrine Hydrochloride	2	0.0	2	100.0
2160003	Vasoconstrictors	Sumatriptan Succinate	2	0.0	2	100.0
2160005	Vasoconstrictors	Eletriptan Hydrobromide	1	0.0	1	100.0
2160402	Vasoconstrictors	Sumatriptan Succinate	1	0.0	1	100.0
116	Antiparkinsonian agents	—	13	0.2	13	100.0
1169101	Antiparkinsonian agents	Levodopa/Carbidopa Hydrate	8	0.1	8	100.0
1169100	Antiparkinsonian agents	Levodopa/Benserazide Hydrochloride	3	0.0	3	100.0
1169017	Antiparkinsonian agents	Rasagiline Mesilate	2	0.0	2	100.0
1161001	Antiparkinsonian agents	Amantadine Hydrochloride	1	0.0	1	100.0
1169006	Antiparkinsonian agents	Droxidopa	1	0.0	1	100.0
1169008	Antiparkinsonian agents	Pergolide Mesilate	1	0.0	1	100.0
1169010	Antiparkinsonian agents	Selegiline Hydrochloride	1	0.0	1	100.0
1169012	Antiparkinsonian agents	Pramipexole Hydrochloride Hydrate	1	0.0	1	100.0
1169015	Antiparkinsonian agents	Zonisamide	1	0.0	1	100.0
1169016	Antiparkinsonian agents	Istradefylline	1	0.0	1	100.0
1169018	Antiparkinsonian agents	Safinamide Mesilate	1	0.0	1	100.0
1169102	Antiparkinsonian agents	Levodopa/Carbidopa Hydrate/Entacapone	1	0.0	1	100.0
211	Cardiotonics	—	13	0.2	10	76.9
2113004	Cardiotonics	Digoxin	9	0.1	6	66.7
2115004	Cardiotonics	Caffeine Hydrate	3	0.0	3	100.0
2119006	Cardiotonics	Pimobendan	1	0.0	1	100.0
316	Vitamin K preparations	—	13	0.2	13	100.0
3160002	Vitamin K preparations	Menatrenone	13	0.2	13	100.0
233	Stomachics and digestives	—	12	0.2	11	91.7
2339177	Stomachics and digestives	Taka-diastase/Crude Drug Combination	3	0.0	3	100.0
2339113	Stomachics and digestives	Sanatace Combination	2	0.0	1	50.0
2339149	Stomachics and digestives	Diastase Combination (1)	2	0.0	2	100.0
2339266	Stomachics and digestives	Powdered Glycyrrhiza Combination (3)	2	0.0	2	100.0
2331003	Stomachics and digestives	Diastase	1	0.0	1	100.0
2339108	Stomachics and digestives	Swertia and Sodium Bicarbonate	1	0.0	1	100.0
2339163	Stomachics and digestives	Pancreatic Digestive Enzyme Combination (1)	1	0.0	1	100.0
2339189	Stomachics and digestives	Taka-diastase/Crude Drug Combination (10)	1	0.0	1	100.0
269	Epidermides-Miscellaneous	—	12	0.2	12	100.0
2699709	Epidermides-Miscellaneous	Tacrolimus Hydrate	5	0.1	5	100.0
2691701	Epidermides-Miscellaneous	Calcipotriol	2	0.0	2	100.0
2699703	Epidermides-Miscellaneous	Bucladesine Sodium	1	0.0	1	100.0
2699711	Epidermides-Miscellaneous	Adapalene	1	0.0	1	100.0
2699712	Epidermides-Miscellaneous	Benzoyl peroxide	1	0.0	1	100.0
2699714	Epidermides-Miscellaneous	Delgocitinib	1	0.0	1	100.0
2699715	Epidermides-Miscellaneous	Difamylast	1	0.0	1	100.0
2699802	Epidermides-Miscellaneous	Calcipotriol Hydrate/Betamethasone Dipropionate	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
312	Vitamin B1 preparations	—	12	0.2	12	100.0
3122007	Vitamin B1 preparations	Fursultiamine	11	0.1	11	100.0
3121	Vitamin B1 preparations	Vitamin B1 preparations	1	0.0	1	100.0
247	Estrogen and progesterone preparations	—	11	0.1	11	100.0
2478002	Estrogen and progesterone preparations	Medroxyprogesterone Acetate	4	0.1	4	100.0
2478003	Estrogen and progesterone preparations	Dydrogesterone	4	0.1	4	100.0
2473001	Estrogen and progesterone preparations	Estradiol	2	0.0	2	100.0
2473700	Estrogen and progesterone preparations	Estradiol	2	0.0	2	100.0
2475001	Estrogen and progesterone preparations	Estril	2	0.0	2	100.0
2479004	Estrogen and progesterone preparations	Estrogen [Conjugated]	2	0.0	2	100.0
441	Antihistamines	—	11	0.1	10	90.9
4419002	Antihistamines	d-Chlorpheniramine Maleate	7	0.1	7	100.0
4413004	Antihistamines	Megitazine	2	0.0	2	100.0
4419003	Antihistamines	Chlorpheniramine Maleate	1	0.0	1	100.0
4419008	Antihistamines	Clemastine Fumarate	1	0.0	0	0.0
624	Synthetic antibacterials	—	11	0.1	11	100.0
6241013	Synthetic antibacterials	Levofloxacin Hydrate	3	0.0	3	100.0
6241017	Synthetic antibacterials	Garenoxacin Mesilate Hydrate	2	0.0	2	100.0
6241018	Synthetic antibacterials	Sitafloxacin Hydrate	2	0.0	2	100.0
6241019	Synthetic antibacterials	Rasucifloxacin Hydrochloride	2	0.0	2	100.0
6241010	Synthetic antibacterials	Tosufloxacin Tosilate Hydrate	1	0.0	1	100.0
6241016	Synthetic antibacterials	Moxifloxacin Hydrochloride	1	0.0	1	100.0
392	Antidotes	—	10	0.1	8	80.0
3929007	Antidotes	Zinc Acetate Hydrate	7	0.1	5	71.4
3922001	Antidotes	Glutathione	2	0.0	2	100.0
3929003	Antidotes	Spherical Carbonaceous Adsorbent	1	0.0	1	100.0
118	Common cold drugs	—	9	0.1	9	100.0
1180107	Common cold drugs	Non-pyrine Common Cold Drugs (4)	5	0.1	5	100.0
118	Common cold drugs	Common cold drugs	4	0.1	4	100.0
121	Local anesthetics	—	9	0.1	8	88.9
1214401	Local anesthetics	Lidocaine	7	0.1	6	85.7
1211401	Local anesthetics	Procaine Hydrochloride	1	0.0	1	100.0
1219002	Local anesthetics	Oxethazaine	1	0.0	1	100.0
315	Vitamin E preparations	—	9	0.1	8	88.9
3150002	Vitamin E preparations	Tocopherol Acetate	9	0.1	8	88.9
265	Antiparasitic dermatosis agents	—	8	0.1	5	62.5
2655709	Antiparasitic dermatosis agents	Ketoconazole	3	0.0	1	33.3
2655712	Antiparasitic dermatosis agents	Luliconazole	3	0.0	2	66.7
2652701	Antiparasitic dermatosis agents	Salicylic Acid	1	0.0	1	100.0
2655710	Antiparasitic dermatosis agents	Lanconazole	1	0.0	1	100.0
2659710	Antiparasitic dermatosis agents	Terbinafine Hydrochloride	1	0.0	1	100.0
224	Antitussives and expectorants	—	7	0.1	6	85.7
2249003	Antitussives and expectorants	Tipipidine Hibenazate	4	0.1	3	75.0
2249001	Antitussives and expectorants	Eprazinone Hydrochloride	2	0.0	2	100.0
2249	Antitussives and expectorants	Other Antitussives And Expectorants	1	0.0	1	100.0
325	Protein and amino acid preparations	—	7	0.1	6	85.7
3259600	Protein and amino acid preparations	Placental Villous Degradants	5	0.1	5	100.0
3253003	Protein and amino acid preparations	Isoleucine/Leucine/Valine	1	0.0	1	100.0
3259108	Protein and amino acid preparations	Elemental Diet for Hepatic Failure (1)	1	0.0	1	100.0
3259109	Protein and amino acid preparations	Enteral Elemental Diet (2-1)	1	0.0	0	0.0
622	Tuberculosis preparations	—	7	0.1	7	100.0
6225001	Tuberculosis preparations	Ethambutol Hydrochloride	4	0.1	4	100.0
6222002	Tuberculosis preparations	Isoniazid	3	0.0	3	100.0
123	Autonomic nervous system agents	—	6	0.1	6	100.0
1231004	Autonomic nervous system agents	Bethanechol Chloride	2	0.0	2	100.0
1231014	Autonomic nervous system agents	Distigmine Bromide	2	0.0	2	100.0
1231008	Autonomic nervous system agents	Propantheline Bromide	1	0.0	1	100.0
1231009	Autonomic nervous system agents	Mepenzolate Bromide	1	0.0	1	100.0
1239003	Autonomic nervous system agents	Pyridostigmine Bromide	1	0.0	1	100.0
226	Gargles	—	6	0.1	6	100.0
2260700	Gargles	Sodium Gualenate Hydrate	4	0.1	4	100.0
2260701	Gargles	Povidone-Iodine	2	0.0	2	100.0
290	Other agents affecting individual organs	—	6	0.1	5	83.3
2900001	Other agents affecting individual organs	Cepharanthine	5	0.1	4	80.0
2900002	Other agents affecting individual organs	Gamma Oryzanol	1	0.0	1	100.0
255	Hemorrhoidal preparations	—	5	0.1	4	80.0
2559101	Hemorrhoidal preparations	Bromelain/Tocopherol Acetate	4	0.1	3	75.0
2559700	Hemorrhoidal preparations	Killed Escherichia Coli	1	0.0	1	100.0
263	Suppurative dermatosis agents	—	5	0.1	5	100.0
2639701	Suppurative dermatosis agents	Ozenoxacin	2	0.0	2	100.0
2634708	Suppurative dermatosis agents	Sodium Fusidate	1	0.0	1	100.0
2634710	Suppurative dermatosis agents	Gentamicin Sulfate	1	0.0	1	100.0
2639805	Suppurative dermatosis agents	Bacitracin/Pradimycin Sulfate	1	0.0	1	100.0
510	Crude drugs	—	5	0.1	5	100.0
5100180	Crude drugs	Coix Seed	4	0.1	4	100.0
5100064	Crude drugs	Red Ginseng	1	0.0	1	100.0

Table 5 Drugs used: Number of subjects by drug

As of Sep 8, 2025

Subjects included in safety analysis

Drug code	Drug category	Drug name	Subjects included in safety analysis (n = 7707)			
			Number of subjects	Percentage of subjects (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
590	Other crude drugs and Chinese medicine formulations	—	5	0.1	5	100.0
5900003	Other crude drugs and Chinese medicine formulations	Coix Seed Extract	3	0.0	3	100.0
5900001	Other crude drugs and Chinese medicine formulations	Processed Aconite Root	1	0.0	1	100.0
5900004	Other crude drugs and Chinese medicine formulations	Processed Aconite Root	1	0.0	1	100.0
999	Therapeutic effect unknown	—	5	0.1	4	80.0
GSK95015401	Therapeutic effect unknown	Unknown	5	0.1	4	80.0
319	Miscellaneous vitamins	—	4	0.1	4	100.0
3190001	Miscellaneous vitamins	Biotin	4	0.1	4	100.0
422	Antimetabolites	—	4	0.1	3	75.0
4229401	Antimetabolites	Pemetrexed Sodium Hydrate	2	0.0	2	100.0
4229001	Antimetabolites	Hydroxycarbamide	1	0.0	1	100.0
4229101	Antimetabolites	Tegafur-Gimeracil-Oteracil Potassium Combination	1	0.0	0	0.0
712	Ointment bases	—	4	0.1	3	75.0
7121703	Ointment bases	White Petrolatum	2	0.0	1	50.0
712	Ointment bases	Ointment bases	1	0.0	1	100.0
7129801	Ointment bases	Polyethylene resin/Liquid Paraffin	1	0.0	1	100.0
122	Skeletal muscle relaxants	—	3	0.0	2	66.7
1225001	Skeletal muscle relaxants	Chlorphenesin Carbamate	2	0.0	1	50.0
1225003	Skeletal muscle relaxants	Methocarbamol	1	0.0	1	100.0
266	Emollients	—	3	0.0	3	100.0
2669701	Emollients	Urea	3	0.0	3	100.0
314	Vitamin C preparations	—	3	0.0	3	100.0
3140002	Vitamin C preparations	Ascorbic Acid	3	0.0	3	100.0
811	Opium alkaloids	—	3	0.0	3	100.0
8114003	Opium alkaloids	Morphine Hydrochloride Hydrate	1	0.0	1	100.0
8115001	Opium alkaloids	Codaine Phosphate Hydrate	1	0.0	1	100.0
8119002	Opium alkaloids	Oxycodone Hydrochloride Hydrate	1	0.0	1	100.0
237	Gastrointestinal agents and combinations	—	2	0.0	2	100.0
237	Gastrointestinal agents and combinations	Gastrointestinal agents and combinations	2	0.0	2	100.0
241	Pituitary hormone preparations	—	2	0.0	1	50.0
2419001	Pituitary hormone preparations	Desmopressin Acetate Hydrate	2	0.0	1	50.0
615	Antibiotics-Acting mainly on gram-positive bacteria, gram-negative bacteria, rickettsia and chlamydia	—	2	0.0	1	50.0
6152005	Antibiotics-Acting mainly on gram-positive bacteria, gram-negative bacteria, rickettsia and chlamydia	Minocycline Hydrochloride	2	0.0	1	50.0
821	Synthetic narcotics	—	2	0.0	2	100.0
8219701	Synthetic narcotics	Fentanyl Citrate	2	0.0	2	100.0
27	Dental preparations	—	1	0.0	1	100.0
27	Dental preparations	Dental preparations	1	0.0	1	100.0
44	Allergic agents	—	1	0.0	1	100.0
44	Allergic agents	Allergic agents	1	0.0	1	100.0
62	Chemotherapeutics	—	1	0.0	0	0.0
62	Chemotherapeutics	Chemotherapeutics	1	0.0	0	0.0
125	Diaphoretics, anhidrotics	—	1	0.0	1	100.0
1259700	Diaphoretics, anhidrotics	Sofopyronium Bromide	1	0.0	1	100.0
254	Contraceptives	—	1	0.0	1	100.0
2549791	Contraceptives	Levonorgestrel	1	0.0	1	100.0
331	Blood substitutes	—	1	0.0	1	100.0
3319538	Blood substitutes	Lactated Ringer's Solution (with Maltose)	1	0.0	1	100.0
391	Liver disease agents	—	1	0.0	1	100.0
3914A01	Liver disease agents	Thioctic Acid	1	0.0	1	100.0
424	Antineoplastics-Plant extract preparations	—	1	0.0	1	100.0
4240409	Antineoplastics-Plant extract preparations	Paclitaxel (Albumin-Bound)	1	0.0	1	100.0
616	Antibiotics-Acting mainly on acid-fast bacteria	—	1	0.0	1	100.0
6164001	Antibiotics-Acting mainly on acid-fast bacteria	Rifampicin	1	0.0	1	100.0
617	Antibiotics-Acting mainly on mold	—	1	0.0	1	100.0
6173001	Antibiotics-Acting mainly on mold	Amphotericin B	1	0.0	1	100.0
799	Other agents not mainly for therapeutic purpose-Miscellaneous	—	1	0.0	1	100.0
7990791	Other agents not mainly for therapeutic purpose-Miscellaneous	Nicotine	1	0.0	1	100.0

Table 6 Non-drug therapies administered

As of Sep 8, 2025

Subjects included in safety analysis

Item/Category		Subjects included in safety analysis (n = 7707)			
		Sample size	Percentage of subjects treated (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
Non-drug therapies administered	Dialysis	9	0.1	6	66.7
	Radiotherapy	2	0.0	1	50.0
	Anticoagulant therapy	2	0.0	1	50.0
	Surgery/Other	42	0.5	37	88.1
	CPAP therapy	9	0.1	8	88.9
	Nerve block	6	0.1	6	100.0
	CPAP	3	0.0	2	66.7
	Trigger point block	3	0.0	3	100.0
	Rehabilitation	2	0.0	2	100.0
	Lumbar epidural block	2	0.0	2	100.0
	Endoscopic colonic polypectomy	2	0.0	2	100.0
	C-PAP therapy	1	0.0	1	100.0
	Cryotherapy for warts	1	0.0	1	100.0
	Block injection	1	0.0	1	100.0
	Baker's cystectomy	1	0.0	0	0.0
	Pain therapy	1	0.0	1	100.0
	Mouthpiece	1	0.0	1	100.0
	Musculoskeletal rehabilitation	1	0.0	1	100.0
	Exercise/physical therapy	1	0.0	1	100.0
	Liquid nitrogen	1	0.0	1	100.0
	Intra-shoulder injection	1	0.0	1	100.0
	Lumbar plexus block	1	0.0	1	100.0
	Lumbar epidural block	1	0.0	1	100.0
	Home oxygen therapy	1	0.0	1	100.0
	Stellate ganglion block	1	0.0	1	100.0
	Breast cancer surgery	1	0.0	0	0.0
	Intra-knee injection	1	0.0	1	100.0
	Elbow tendon sheath block	1	0.0	1	100.0
	Bilateral knee joint injection	1	0.0	1	100.0
	Intravenous injection for pain relief and cervical block	1	0.0	0	0.0

Incidence of Adverse Drug Reactions and Infections in Post-marketing Surveillance

Survey/study title: Shingrix for Intramuscular Injection, Drug Use Investigation

	Status of post-marketing surveillance	
Number of subjects included in safety analysis	7707	
Number of subjects with ADRs	6406	
Incidence proportion of ADRs	83.1%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Infections and infestations	13	(0.2)
Conjunctivitis	1	(0.0)
Gastroenteritis	1	(0.0)
Gastroenteritis viral	1	(0.0)
Herpes virus infection	1	(0.0)
Herpes zoster	1	(0.0)
Pustule	1	(0.0)
Rhinitis	2	(0.0)
Cystitis bacterial	1	(0.0)
Oral herpes	4	(0.1)
Blood and lymphatic system disorders	21	(0.3)
Lymph node pain	7	(0.1)
Lymphadenopathy	16	(0.2)
Metabolism and nutrition disorders	26	(0.3)
Decreased appetite	26	(0.3)
Psychiatric disorders	4	(0.1)
Dissociative disorder	1	(0.0)
Euphoric mood	1	(0.0)
Hallucination	1	(0.0)
Listless	1	(0.0)
Nervous system disorders	2564	(33.3)
Dizziness	35	(0.5)
Dizziness postural	1	(0.0)
Dysaesthesia	1	(0.0)
Dysgeusia	1	(0.0)
Head discomfort	2	(0.0)
Headache	2538	(32.9)
Hypoaesthesia	10	(0.1)
Migraine	1	(0.0)
Movement disorder	1	(0.0)
Neuralgia	4	(0.1)
Paraesthesia	10	(0.1)
Parosmia	1	(0.0)
Peroneal nerve palsy	1	(0.0)
Somnolence	20	(0.3)
Tremor	1	(0.0)
Balance disorder	7	(0.1)
Taste disorder	2	(0.0)
Brain fog	2	(0.0)

Incidence of Adverse Drug Reactions and Infections in Post-marketing Surveillance

Survey/study title: Shingrix for Intramuscular Injection, Drug Use Investigation

	Status of post-marketing surveillance	
Number of subjects included in safety analysis	7707	
Number of subjects with ADRs	6406	
Incidence proportion of ADRs	83.1%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Eye disorders	14	(0.2)
Eye discharge	2	(0.0)
Eye inflammation	1	(0.0)
Eye irritation	1	(0.0)
Eye pain	4	(0.1)
Retinal haemorrhage	1	(0.0)
Swelling of eyelid	1	(0.0)
Vision blurred	1	(0.0)
Visual acuity reduced	1	(0.0)
Eye pruritus	2	(0.0)
Periorbital swelling	2	(0.0)
Eyelid irritation	1	(0.0)
Eyelid pain	1	(0.0)
Ear and labyrinth disorders	15	(0.2)
Ear pain	4	(0.1)
Tinnitus	6	(0.1)
Hypoacusis	2	(0.0)
Ear discomfort	3	(0.0)
Ear pruritus	2	(0.0)
Cardiac disorders	12	(0.2)
Palpitations	12	(0.2)
Vascular disorders	14	(0.2)
Flushing	1	(0.0)
Hypertension	1	(0.0)
Hypotension	2	(0.0)
Peripheral coldness	5	(0.1)
Hot flush	4	(0.1)
Internal haemorrhage	1	(0.0)
Respiratory, thoracic and mediastinal disorders	39	(0.5)
Cough	5	(0.1)
Dyspnoea	4	(0.1)
Epistaxis	3	(0.0)
Nasal congestion	1	(0.0)
Productive cough	2	(0.0)
Rhinorrhoea	10	(0.1)
Sneezing	3	(0.0)
Yawning	2	(0.0)
Upper respiratory tract inflammation	1	(0.0)
Oropharyngeal discomfort	3	(0.0)
Oropharyngeal pain	13	(0.2)
Nasal pruritus	1	(0.0)

Incidence of Adverse Drug Reactions and Infections in Post-marketing Surveillance

Survey/study title: Shingrix for Intramuscular Injection, Drug Use Investigation

	Status of post-marketing surveillance	
Number of subjects included in safety analysis	7707	
Number of subjects with ADRs	6406	
Incidence proportion of ADRs	83.1%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Gastrointestinal disorders	768	(10.0)
Abdominal discomfort	9	(0.1)
Abdominal pain	287	(3.7)
Abdominal pain upper	11	(0.1)
Cheilitis	1	(0.0)
Constipation	2	(0.0)
Diarrhoea	357	(4.6)
Gingival pain	1	(0.0)
Gingival swelling	2	(0.0)
Glossitis	1	(0.0)
Glossodynia	1	(0.0)
Lip swelling	1	(0.0)
Melaena	1	(0.0)
Nausea	381	(4.9)
Oral discomfort	1	(0.0)
Oral pain	2	(0.0)
Salivary gland pain	2	(0.0)
Stomatitis	9	(0.1)
Tongue rough	1	(0.0)
Toothache	3	(0.0)
Vomiting	84	(1.1)
Lip blister	1	(0.0)
Hypoesthesia oral	1	(0.0)
Paraesthesia oral	1	(0.0)
Tongue exfoliation	1	(0.0)
Oral mucosa erosion	1	(0.0)
Loose tooth	1	(0.0)
Faeces soft	1	(0.0)
Anal incontinence	1	(0.0)
Oral mucosal roughening	1	(0.0)

Incidence of Adverse Drug Reactions and Infections in Post-marketing Surveillance

Survey/study title: Shingrix for Intramuscular Injection, Drug Use Investigation

	Status of post-marketing surveillance	
Number of subjects included in safety analysis	7707	
Number of subjects with ADRs	6406	
Incidence proportion of ADRs	83.1%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Skin and subcutaneous tissue disorders	162	(2.1)
Blister	2	(0.0)
Dermatitis contact	1	(0.0)
Eczema	9	(0.1)
Erythema	11	(0.1)
Night sweats	2	(0.0)
Pain of skin	2	(0.0)
Perioral dermatitis	2	(0.0)
Pruritus	106	(1.4)
Purpura	1	(0.0)
Rash	21	(0.3)
Rash erythematous	2	(0.0)
Rash pruritic	1	(0.0)
Scab	1	(0.0)
Skin discolouration	1	(0.0)
Urticaria	15	(0.2)
Skin tightness	2	(0.0)
Skin induration	1	(0.0)
Skin burning sensation	2	(0.0)
Butterfly rash	1	(0.0)
Circumoral swelling	1	(0.0)
Musculoskeletal and connective tissue disorders	3161	(41.0)
Arthralgia	86	(1.1)
Back pain	34	(0.4)
Bone pain	2	(0.0)
Flank pain	1	(0.0)
Groin pain	1	(0.0)
Muscle spasms	6	(0.1)
Muscular weakness	3	(0.0)
Musculoskeletal pain	5	(0.1)
Myalgia	3125	(40.5)
Neck pain	10	(0.1)
Pain in extremity	15	(0.2)
Rheumatoid arthritis	1	(0.0)
Muscle tightness	3	(0.0)
Musculoskeletal chest pain	2	(0.0)
Musculoskeletal stiffness	15	(0.2)
Renal and urinary disorders	10	(0.1)
Haematuria	1	(0.0)
Nocturia	3	(0.0)
Pollakiuria	4	(0.1)
Polyuria	1	(0.0)
Urethral pain	1	(0.0)
Urinary incontinence	1	(0.0)

Incidence of Adverse Drug Reactions and Infections in Post-marketing Surveillance

Survey/study title: Shingrix for Intramuscular Injection, Drug Use Investigation

	Status of post-marketing surveillance	
Number of subjects included in safety analysis	7707	
Number of subjects with ADRs	6406	
Incidence proportion of ADRs	83.1%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
General disorders and administration site conditions	6365	(82.6)
Asthenia	5	(0.1)
Chest pain	13	(0.2)
Chills	1400	(18.2)
Condition aggravated	2	(0.0)
Discomfort	1	(0.0)
Facial pain	1	(0.0)
Fatigue	3154	(40.9)
Feeling abnormal	7	(0.1)
Feeling cold	2	(0.0)
Feeling hot	5	(0.1)
Injection site paraesthesia	1	(0.0)
Malaise	44	(0.6)
Mass	1	(0.0)
Oedema peripheral	3	(0.0)
Pain	12	(0.2)
Pyrexia	3101	(40.2)
Swelling	7	(0.1)
Swelling face	2	(0.0)
Thirst	6	(0.1)
Axillary pain	11	(0.1)
Peripheral swelling	4	(0.1)
Injected limb mobility decreased	1	(0.0)
Vaccination site erythema	4070	(52.8)
Vaccination site reaction	1	(0.0)
Vaccination site induration	3	(0.0)
Vaccination site pain	6070	(78.8)
Vaccination site pruritus	222	(2.9)
Vaccination site discolouration	3	(0.0)
Vaccination site haemorrhage	1	(0.0)
Vaccination site discomfort	1	(0.0)
Vaccination site rash	1	(0.0)
Vaccination site bruising	2	(0.0)
Vaccination site swelling	4191	(54.4)
Vaccination site vesicles	1	(0.0)
Vaccination site warmth	12	(0.2)
Vaccination site eczema	2	(0.0)
Vaccination site mass	1	(0.0)
Investigations	7	(0.1)
Blood pressure increased	3	(0.0)
C-reactive protein increased	1	(0.0)
Heart rate	1	(0.0)
Heart rate increased	2	(0.0)
Oxygen saturation	1	(0.0)
Injury, poisoning and procedural complications	1	(0.0)
Heat illness	1	(0.0)

MedDRA/J (28.0)

Table 7-1 Incidence of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Sample size	7707					
Number of subjects with ADRs	6394	0	754	5	6406	5
Incidence proportion of ADRs (%)	83.0	0.0	9.8	0.1	83.1	0.1
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
General disorders and administration site conditions	6362 (82.5)	0 (0.0)	364 (4.7)	0 (0.0)	6365 (82.6)	0 (0.0)
Vaccination site pain	6067 (78.7)	0 (0.0)	16 (0.2)	0 (0.0)	6070 (78.8)	0 (0.0)
Vaccination site swelling	4188 (54.3)	0 (0.0)	11 (0.1)	0 (0.0)	4191 (54.4)	0 (0.0)
Vaccination site erythema	4067 (52.8)	0 (0.0)	13 (0.2)	0 (0.0)	4070 (52.8)	0 (0.0)
Fatigue	3149 (40.9)	0 (0.0)	14 (0.2)	0 (0.0)	3154 (40.9)	0 (0.0)
Pyrexia	3097 (40.2)	0 (0.0)	8 (0.1)	0 (0.0)	3101 (40.2)	0 (0.0)
Chills	1398 (18.1)	0 (0.0)	6 (0.1)	0 (0.0)	1400 (18.2)	0 (0.0)
Vaccination site pruritus	0 (0.0)	0 (0.0)	222 (2.9)	0 (0.0)	222 (2.9)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	44 (0.6)	0 (0.0)	44 (0.6)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	13 (0.2)	0 (0.0)	13 (0.2)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)	11 (0.1)	0 (0.0)
Feeling abnormal	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Swelling	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Asthenia	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Peripheral swelling	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site induration	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Condition aggravated	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Feeling cold	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Facial pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injection site paraesthesia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Mass	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injected limb mobility decreased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site reaction	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site mass	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	3119 (40.5)	0 (0.0)	165 (2.1)	1 (0.0)	3161 (41.0)	1 (0.0)
Myalgia	3119 (40.5)	0 (0.0)	10 (0.1)	0 (0.0)	3125 (40.5)	0 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	86 (1.1)	0 (0.0)	86 (1.1)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	34 (0.4)	0 (0.0)	34 (0.4)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Neck pain	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)

Table 7-1 Incidence of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Sample size	7707					
Number of subjects with ADRs	6394	0	754	5	6406	5
Incidence proportion of ADRs (%)	83.0	0.0	9.8	0.1	83.1	0.1
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
Nervous system disorders	2535 (32.9)	0 (0.0)	102 (1.3)	0 (0.0)	2564 (33.3)	0 (0.0)
Headache	2535 (32.9)	0 (0.0)	11 (0.1)	0 (0.0)	2538 (32.9)	0 (0.0)
Dizziness	0 (0.0)	0 (0.0)	35 (0.5)	0 (0.0)	35 (0.5)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	20 (0.3)	0 (0.0)	20 (0.3)	0 (0.0)
Hypoaesthesia	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Parosmia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tremor	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastrointestinal disorders	729 (9.5)	0 (0.0)	64 (0.8)	1 (0.0)	768 (10.0)	1 (0.0)
Nausea	377 (4.9)	0 (0.0)	4 (0.1)	0 (0.0)	381 (4.9)	0 (0.0)
Diarrhoea	352 (4.6)	0 (0.0)	8 (0.1)	0 (0.0)	357 (4.6)	0 (0.0)
Abdominal pain	284 (3.7)	0 (0.0)	4 (0.1)	0 (0.0)	287 (3.7)	0 (0.0)
Vomiting	81 (1.1)	0 (0.0)	3 (0.0)	0 (0.0)	84 (1.1)	0 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)	11 (0.1)	0 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gingival pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Melaena	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Oral discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip blister	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypoaesthesia oral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-1 Incidence of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Sample size	7707					
Number of subjects with ADRs	6394	0	754	5	6406	5
Incidence proportion of ADRs (%)	83.0	0.0	9.8	0.1	83.1	0.1
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	162 (2.1)	0 (0.0)	162 (2.1)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	106 (1.4)	0 (0.0)	106 (1.4)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	21 (0.3)	0 (0.0)	21 (0.3)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)	11 (0.1)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Blister	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Purpura	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	39 (0.5)	0 (0.0)	39 (0.5)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	13 (0.2)	0 (0.0)	13 (0.2)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	26 (0.3)	0 (0.0)	26 (0.3)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	26 (0.3)	0 (0.0)	26 (0.3)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	21 (0.3)	0 (0.0)	21 (0.3)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	16 (0.2)	0 (0.0)	16 (0.2)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Hypoacusis	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)

Table 7-1 Incidence of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Sample size	7707					
Number of subjects with ADRs	6394	0	754	5	6406	5
Incidence proportion of ADRs (%)	83.0	0.0	9.8	0.1	83.1	0.1
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
Eye disorders	0 (0.0)	0 (0.0)	14 (0.2)	1 (0.0)	14 (0.2)	1 (0.0)
Eye pain	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	14 (0.2)	1 (0.0)	14 (0.2)	1 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Infections and infestations	0 (0.0)	0 (0.0)	13 (0.2)	0 (0.0)	13 (0.2)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Investigations	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	4 (0.1)	1 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Listless	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

*The following adverse drug reactions occurred within 7 days after Shingrix vaccination (up to Day 7 when the day of vaccination defined as Day 1)

MedDRA/J (28.0)

Local: injection site pain, injection site redness, and injection site swelling

Systemic: myalgia, fatigue, headache, chills, pyrexia, and gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain)

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Solicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	0						6394					
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	464	5929	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Infections and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Listless	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nervous system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	118 (1.5)	2416 (31.3)	1 (0.0)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Headache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	118 (1.5)	2416 (31.3)	1 (0.0)
Hypoaesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parosmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tremor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Solicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	0						6394					
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	464	5929	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Solicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	0						6394					
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	464	5929	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Gastrointestinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	29 (0.4)	700 (9.1)	0 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	272 (3.5)	2 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	17 (0.2)	335 (4.3)	0 (0.0)
Gingival pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Melaina	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	363 (4.7)	0 (0.0)
Oral discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	80 (1.0)	0 (0.0)
Lip blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Purpura	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Solicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	0						6394					
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	464	5929	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Musculoskeletal and connective tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	139 (1.8)	2978 (38.6)	2 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myalgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	139 (1.8)	2978 (38.6)	2 (0.0)
Neck pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Solicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	0						6394					
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	464	5929	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
General disorders and administration site conditions	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	428 (5.6)	5933 (77.0)	1 (0.0)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chills	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	42 (0.5)	1355 (17.6)	1 (0.0)
Condition aggravated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Facial pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	135 (1.8)	3012 (39.1)	2 (0.0)
Feeling abnormal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling cold	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Injection site paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pyrexia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	122 (1.6)	2974 (38.6)	1 (0.0)
Swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Injected limb mobility decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	208 (2.7)	3858 (50.1)	1 (0.0)
Vaccination site reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	289 (3.7)	5777 (75.0)	1 (0.0)
Vaccination site pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	201 (2.6)	3986 (51.7)	1 (0.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Solicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	0						6394					
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	464	5929	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Investigations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

If multiple events with the same PT occur in the same subject, the events will be tabulated based on the following priority: (1) Serious > Non-serious, and (2) Death > Recovered with sequelae > Not recovered > Recovering > Recovered > Unknown.

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Unsolicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						749					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	49	698	2
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Infections and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	11 (0.1)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Pastule	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	20 (0.3)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	15 (0.2)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	24 (0.3)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	24 (0.3)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Listless	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nervous system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	93 (1.2)	1 (0.0)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	32 (0.4)	0 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Headache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)
Hypoesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)
Parosmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	18 (0.2)	0 (0.0)
Tremor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	5 (0.1)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Unsolicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						749					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	49	698	2
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	12 (0.2)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	14 (0.2)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	10 (0.1)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	10 (0.1)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	12 (0.2)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	36 (0.5)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	9 (0.1)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	12 (0.2)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Unsolicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						749					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	49	698	2
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Gastrointestinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	62 (0.8)	1 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)
Abdominal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Diarrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)
Gingival pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Melaena	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Oral discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)
Vomiting	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Lip blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypoesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (0.2)	145 (1.9)	1 (0.0)
Blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	96 (1.2)	0 (0.0)
Purpura	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	19 (0.2)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	9 (0.1)	1 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Unsolicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						749					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	49	698	2
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Musculoskeletal and connective tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	155 (2.0)	0 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	84 (1.1)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	32 (0.4)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	4 (0.1)	0 (0.0)
Myalgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)
Neck pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	9 (0.1)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	12 (0.2)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Unsolicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						749					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	49	698	2
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
General disorders and administration site conditions	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (0.2)	347 (4.5)	2 (0.0)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	11 (0.1)	1 (0.0)
Chills	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Condition aggravated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Facial pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Fatigue	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	0 (0.0)
Feeling abnormal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)
Feeling cold	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Injection site paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	40 (0.5)	1 (0.0)
Mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	11 (0.1)	0 (0.0)
Pyrexia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)
Swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	10 (0.1)	0 (0.0)
Peripheral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Injected limb mobility decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.2)	0 (0.0)
Vaccination site reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (0.2)	0 (0.0)
Vaccination site pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	217 (2.8)	0 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Vaccination site swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	10 (0.1)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

Subjects included in safety analysis

	Unsolicited adverse events											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						749					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	49	698	2
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Investigations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	6 (0.1)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

If multiple events with the same PT occur in the same

Note) If the onset date of an ADR was unknown and :

Table 7-2 Outcome of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Combined total											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						6401					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	484	5916	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Infections and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	11 (0.1)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Pastule	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	20 (0.3)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	15 (0.2)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	24 (0.3)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	24 (0.3)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Listless	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nervous system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	124 (1.6)	2439 (31.6)	1 (0.0)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	32 (0.4)	0 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Headache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	118 (1.5)	2419 (31.4)	1 (0.0)
Hypoesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)
Parosmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	18 (0.2)	0 (0.0)
Tremor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	5 (0.1)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Combined total											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						6401					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	484	5916	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	12 (0.2)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	14 (0.2)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	10 (0.1)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	10 (0.1)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	12 (0.2)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	36 (0.5)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	9 (0.1)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	12 (0.2)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Combined total											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						6401					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	484	5916	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Gastrointestinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	29 (0.4)	738 (9.6)	0 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)
Abdominal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	275 (3.6)	2 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Diarrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	17 (0.2)	340 (4.4)	0 (0.0)
Gingival pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Melaena	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	367 (4.8)	0 (0.0)
Oral discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)
Vomiting	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	83 (1.1)	0 (0.0)
Lip blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypoesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (0.2)	145 (1.9)	1 (0.0)
Blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	96 (1.2)	0 (0.0)
Purpura	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	19 (0.2)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	9 (0.1)	1 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Combined total											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						6401					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	484	5916	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Musculoskeletal and connective tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	142 (1.8)	3016 (39.1)	2 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	84 (1.1)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	32 (0.4)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	4 (0.1)	0 (0.0)
Myalgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	139 (1.8)	2984 (38.7)	2 (0.0)
Neck pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	9 (0.1)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	12 (0.2)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Combined total											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						6401					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	484	5916	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
General disorders and administration site conditions	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	433 (5.6)	5931 (77.0)	1 (0.0)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	11 (0.1)	1 (0.0)
Chills	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	42 (0.5)	1357 (17.6)	1 (0.0)
Condition aggravated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Facial pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Fatigue	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	135 (1.8)	3017 (39.1)	2 (0.0)
Feeling abnormal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)
Feeling cold	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Injection site paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	40 (0.5)	1 (0.0)
Mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	11 (0.1)	0 (0.0)
Pyrexia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	122 (1.6)	2978 (38.6)	1 (0.0)
Swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	10 (0.1)	0 (0.0)
Peripheral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Injected limb mobility decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	208 (2.7)	3861 (50.1)	1 (0.0)
Vaccination site reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	289 (3.7)	5780 (75.0)	1 (0.0)
Vaccination site pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	217 (2.8)	0 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Vaccination site swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	201 (2.6)	3989 (51.8)	1 (0.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	10 (0.1)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-2 Outcome of ADRs by seriousness

As of Sep 8, 2025

Subjects included in safety analysis

	Combined total											
	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707											
Number of subjects with ADRs (by seriousness)	5						6401					
Number of subjects with ADRs	0	0	0	1	4	0	0	0	0	484	5916	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Investigations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	6 (0.1)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

MedDRA/J (28.0)

If multiple events with the same PT occur in the same

Note) If the onset date of an ADR was unknown and :

Table 7-3 Severity classification of adverse events

<Severity>

Adverse event term	Grade	
Injection site redness Injection site swelling	0	Diameter: <2 cm
	1	Diameter: ≥ 2 cm and ≤ 5 cm
	2	Diameter: >5 cm and ≤ 10 cm
	3	Diameter: >10 cm
Pyrexia	0	< 37.5°C
	1	37.5°C to 38.0°C
	2	38.1°C to 39.0°C
	3	>39.0°C
Other adverse events	0	Normal (no symptoms)
	1	Mild: Easily tolerable
	2	Moderate: Interferes with daily activities
	3	Severe: Unable to perform daily activities

Table 7-4 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events					Unsolicited adverse events					Combined*				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Sample size	7707					7707					7707				
Number of subjects with ADRs (solicited/unsolicited)	6394					754					6406				
Number of subjects with ADRs	40	2889	2355	885	25	1	545	160	34	14	37	2881	2567	896	25
Incidence proportion of ADRs (%)	0.5	37.5	33.2	11.5	0.3	0.0	7.1	2.1	0.4	0.2	0.5	37.4	33.3	11.6	0.3
Type of ADR	Number of subjects with ADRs (%)					Number of subjects with ADRs (%)					Number of subjects with ADRs (%)				
Infections and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	6 (0.1)	5 (0.1)	1 (0.0)	1 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	7 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	7 (0.1)	0 (0.0)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	4 (0.1)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (0.2)	5 (0.1)	1 (0.0)	2 (0.0)	0 (0.0)	18 (0.2)	5 (0.1)	1 (0.0)	2 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (0.2)	5 (0.1)	1 (0.0)	2 (0.0)	0 (0.0)	18 (0.2)	5 (0.1)	1 (0.0)	2 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Listless	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nervous system disorders	1 (0.0)	1788 (23.2)	609 (7.9)	105 (1.4)	32 (0.4)	0 (0.0)	65 (0.8)	29 (0.4)	5 (0.1)	3 (0.0)	1 (0.0)	1795 (23.3)	626 (8.1)	109 (1.4)	33 (0.4)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (0.3)	11 (0.1)	3 (0.0)	1 (0.0)	0 (0.0)	20 (0.3)	11 (0.1)	3 (0.0)	1 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Headache	1 (0.0)	1788 (23.2)	609 (7.9)	105 (1.4)	32 (0.4)	0 (0.0)	9 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1790 (23.2)	609 (7.9)	106 (1.4)	32 (0.4)
Hypoesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Parosmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	6 (0.1)	1 (0.0)	2 (0.0)	0 (0.0)	11 (0.1)	6 (0.1)	1 (0.0)	2 (0.0)
Tremor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)

Table 7-4 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events					Unsolicited adverse events					Combined*				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Sample size	7707					7707					7707				
Number of subjects with ADRs (solicited/unsolicited)	6394					754					6406				
Number of subjects with ADRs	40	2889	2355	885	25	1	545	160	34	14	37	2881	2567	896	25
Incidence proportion of ADRs (%)	0.5	37.5	33.2	11.5	0.3	0.0	7.1	2.1	0.4	0.2	0.5	37.4	33.3	11.6	0.3
Type of ADR	Number of subjects with ADRs (%)					Number of subjects with ADRs (%)					Number of subjects with ADRs (%)				
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	3 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	8 (0.1)	3 (0.0)	2 (0.0)	1 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	3 (0.0)	0 (0.0)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	33 (0.4)	5 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	33 (0.4)	5 (0.1)	1 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 7-4 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events					Unsolicited adverse events					Combined*				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Sample size	7707					7707					7707				
Number of subjects with ADRs (solicited/unsolicited)	6394					754					6406				
Number of subjects with ADRs	40	2889	2355	885	25	1	545	160	34	14	37	2881	2567	896	25
Incidence proportion of ADRs (%)	0.5	37.5	33.2	11.5	0.3	0.0	7.1	2.1	0.4	0.2	0.5	37.4	33.3	11.6	0.3
Type of ADR	Number of subjects with ADRs (%)					Number of subjects with ADRs (%)					Number of subjects with ADRs (%)				
Gastrointestinal disorders	0 (0.0)	566 (7.3)	129 (1.7)	25 (0.3)	9 (0.1)	0 (0.0)	48 (0.6)	11 (0.1)	4 (0.1)	1 (0.0)	0 (0.0)	593 (7.7)	138 (1.8)	27 (0.4)	10 (0.1)
Abdominal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain	0 (0.0)	225 (2.9)	45 (0.6)	6 (0.1)	8 (0.1)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	226 (2.9)	46 (0.6)	6 (0.1)	9 (0.1)
Abdominal pain upper	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	0 (0.0)	293 (3.8)	48 (0.6)	7 (0.1)	4 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	297 (3.9)	48 (0.6)	8 (0.1)	4 (0.1)
Gingival pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Melasma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	0 (0.0)	284 (3.7)	70 (0.9)	15 (0.2)	8 (0.1)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	286 (3.7)	71 (0.9)	15 (0.2)	9 (0.1)
Oral discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vomiting	0 (0.0)	48 (0.6)	21 (0.3)	7 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	48 (0.6)	22 (0.3)	8 (0.1)	6 (0.1)
Lip blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 7-4 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events					Unsolicited adverse events					Combined*				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Sample size	7707					7707					7707				
Number of subjects with ADRs (solicited/unsolicited)	6394					754					6466				
Number of subjects with ADRs	40	2889	2355	885	25	1	545	160	34	14	37	2881	2567	896	25
Incidence proportion of ADRs (%)	0.5	37.5	33.2	11.5	0.3	0.0	7.1	2.1	0.4	0.2	0.5	37.4	33.3	11.6	0.3
Type of ADR	Number of subjects with ADRs (%)					Number of subjects with ADRs (%)					Number of subjects with ADRs (%)				
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	139 (1.8)	18 (0.2)	1 (0.0)	4 (0.1)	0 (0.0)	139 (1.8)	18 (0.2)	1 (0.0)	4 (0.1)
Blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	92 (1.2)	12 (0.2)	1 (0.0)	1 (0.0)	0 (0.0)	92 (1.2)	12 (0.2)	1 (0.0)	1 (0.0)
Purpura	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (0.2)	3 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	16 (0.2)	3 (0.0)	0 (0.0)	2 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	12 (0.2)	2 (0.0)	0 (0.0)	1 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	1 (0.0)	2336 (30.3)	617 (8.0)	120 (1.6)	45 (0.6)	0 (0.0)	89 (1.2)	59 (0.8)	15 (0.2)	2 (0.0)	1 (0.0)	2344 (30.4)	645 (8.4)	127 (1.6)	44 (0.6)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	48 (0.6)	28 (0.4)	9 (0.1)	1 (0.0)	0 (0.0)	48 (0.6)	28 (0.4)	9 (0.1)	1 (0.0)
Back pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	17 (0.2)	16 (0.2)	1 (0.0)	0 (0.0)	0 (0.0)	17 (0.2)	16 (0.2)	1 (0.0)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)
Myalgia	1 (0.0)	2336 (30.3)	617 (8.0)	120 (1.6)	45 (0.6)	0 (0.0)	7 (0.1)	1 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	2339 (30.3)	618 (8.0)	122 (1.6)	45 (0.6)
Neck pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	2 (0.0)	1 (0.0)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	4 (0.1)	2 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 7-4 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

	Solicited adverse events						Unsolicited adverse events						Combined*					
	Severity						Severity						Severity					
	0	1	2	3	Unknown		0	1	2	3	Unknown		0	1	2	3	Unknown	
Sample size	7707						7707						7707					
Number of subjects with ADRs (solicited/unsolicited)	6394						754						6406					
Number of subjects with ADRs	40	2889	2355	885	25		1	545	160	34	14		37	2881	2567	896	25	
Incidence proportion of ADRs (%)	0.5	37.5	33.2	11.5	0.3		0.0	7.1	2.1	0.4	0.2		0.5	37.4	33.3	11.6	0.3	
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
General disorders and administration site conditions	45 (0.6)	2966 (38.5)	2490 (32.3)	837 (10.9)	24 (0.3)		1 (0.0)	296 (3.8)	55 (0.7)	7 (0.1)	5 (0.1)		44 (0.6)	2960 (38.4)	2496 (32.4)	841 (10.9)	24 (0.3)	
Asthma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	
Chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		1 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)		1 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	
Chills	0 (0.0)	938 (12.2)	335 (4.3)	106 (1.4)	19 (0.2)		0 (0.0)	5 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)		0 (0.0)	939 (12.2)	335 (4.3)	107 (1.4)	19 (0.2)	
Condition aggravated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	
Discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Facial pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Fatigue	2 (0.0)	2091 (27.1)	829 (10.8)	182 (2.4)	45 (0.6)		0 (0.0)	13 (0.2)	0 (0.0)	1 (0.0)	0 (0.0)		2 (0.0)	2095 (27.2)	829 (10.8)	183 (2.4)	45 (0.6)	
Feeling abnormal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	7 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	7 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	
Feeling cold	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Feeling hot	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	
Injection site paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Malaise	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	23 (0.3)	17 (0.2)	3 (0.0)	1 (0.0)		0 (0.0)	23 (0.3)	17 (0.2)	3 (0.0)	1 (0.0)	
Mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	6 (0.1)	5 (0.1)	0 (0.0)	1 (0.0)		0 (0.0)	6 (0.1)	5 (0.1)	0 (0.0)	1 (0.0)	
Pyrexia	757 (9.8)	1498 (19.4)	752 (9.8)	61 (0.8)	29 (0.4)		3 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)		758 (9.8)	1500 (19.5)	753 (9.8)	61 (0.8)	29 (0.4)	
Swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)		0 (0.0)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	
Swelling face	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Thirst	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	
Axillary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	7 (0.1)	4 (0.1)	0 (0.0)	0 (0.0)		0 (0.0)	7 (0.1)	4 (0.1)	0 (0.0)	0 (0.0)	
Peripheral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	
Injected limb mobility decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site erythema	587 (7.6)	1659 (21.5)	1306 (16.9)	456 (5.9)	59 (0.8)		1 (0.0)	8 (0.1)	4 (0.1)	0 (0.0)	0 (0.0)		585 (7.6)	1662 (21.6)	1308 (17.0)	456 (5.9)	59 (0.8)	
Vaccination site reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site pain	1 (0.0)	4546 (59.0)	1271 (16.5)	196 (2.5)	53 (0.7)		0 (0.0)	15 (0.2)	0 (0.0)	1 (0.0)	0 (0.0)		1 (0.0)	4548 (59.0)	1271 (16.5)	197 (2.6)	53 (0.7)	
Vaccination site pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	206 (2.7)	14 (0.2)	0 (0.0)	2 (0.0)		0 (0.0)	206 (2.7)	14 (0.2)	0 (0.0)	2 (0.0)	
Vaccination site discoloration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site bruising	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site swelling	615 (8.0)	1969 (25.5)	1189 (15.4)	362 (4.7)	53 (0.7)		0 (0.0)	6 (0.1)	5 (0.1)	0 (0.0)	0 (0.0)		613 (8.0)	1972 (25.6)	1191 (15.5)	362 (4.7)	53 (0.7)	
Vaccination site vesicles	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site warmth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	10 (0.1)	1 (0.0)	0 (0.0)	1 (0.0)		0 (0.0)	10 (0.1)	1 (0.0)	0 (0.0)	1 (0.0)	
Vaccination site eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	
Vaccination site mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Investigations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	6 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)		0 (0.0)	6 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	
Blood pressure increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	
C-reactive protein increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Heart rate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Heart rate increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Oxygen saturation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Heat illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	

*If there are multiple events with the same SOC and PT in the same subject, the events will be adopted based on the following priority: Grade 3 > 2 > 1 > 0 > Unknown.

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

MedDRA/J (28.0)

Attached Form 2-1 The occurrence of solicited ADRs in Phase III studies

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

< Local solicited ADRs >

	Status of phase III studies	
Number of subjects included in safety analysis	6544	
Number of subjects with ADRs	5360	
Incidence proportion of ADRs	81.9%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
General disorders and administration site conditions	5360	(81.9)
Injection site erythema	2450	(37.4)
Injection site pain	5177	(79.1)
Injection site swelling	1585	(24.2)

MedDRA/J version 25.1

< Systemic solicited ADRs >

	Status of phase III studies	
Number of subjects included in safety analysis	6536	
Number of subjects with ADRs	3471	
Incidence proportion of ADRs	53.1%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Gastrointestinal disorder	799	(12.2)
Gastrointestinal disorder	799	(12.2)
General disorders and administration site conditions	2874	(44.0)
Chills	1405	(21.5)
Fatigue	2309	(35.3)
Pyrexia	1094	(16.7)
Musculoskeletal and connective tissue disorders	2451	(37.5)
Myalgia	2451	(37.5)
Nervous system disorder	1870	(28.6)
Headache	1870	(28.6)

MedDRA/J version 25.1

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Blood and lymphatic system disorders	25	(0.2)
Bone marrow failure	1	(0.0)
Febrile neutropenia	1	(0.0)
Lymph node pain	7	(0.0)
Lymphadenitis	2	(0.0)
Lymphadenopathy	13	(0.1)
Neutropenia	5	(0.0)
Cardiac disorders	22	(0.1)
Acute myocardial infarction	1	(0.0)
Angina pectoris	1	(0.0)
Arrhythmia	2	(0.0)
Cardiac flutter	1	(0.0)
Palpitations	11	(0.1)
Tachycardia	6	(0.0)
Ear and labyrinth disorders	29	(0.2)
Ear pain	6	(0.0)
Middle ear effusion	1	(0.0)
Tinnitus	5	(0.0)
Vertigo	17	(0.1)
Eye disorders	21	(0.1)
Conjunctival haemorrhage	1	(0.0)
Dark circles under eyes	1	(0.0)
Eye irritation	1	(0.0)
Eye pain	7	(0.0)
Eye pruritus	3	(0.0)
Eye swelling	1	(0.0)
Eyelids pruritus	1	(0.0)
Ocular hyperaemia	3	(0.0)
Periorbital oedema	1	(0.0)
Periorbital swelling	1	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Photopsia	1	(0.0)
Swelling of eyelid	2	(0.0)
Vision blurred	1	(0.0)
Gastrointestinal disorder	299	(1.8)
Abdominal discomfort	4	(0.0)
Abdominal distension	2	(0.0)
Abdominal pain	17	(0.1)
Abdominal pain upper	22	(0.1)
Aphthous ulcer	1	(0.0)
Cheilitis	1	(0.0)
Colitis ulcerative	1	(0.0)
Constipation	3	(0.0)
Diarrhoea	46	(0.3)
Dry mouth	7	(0.0)
Dyspepsia	8	(0.1)
Flatulence	1	(0.0)
Gastritis	1	(0.0)
Gastrointestinal disorder	7	(0.0)
Glossodynia	2	(0.0)
Hypoaesthesia oral	1	(0.0)
Lip disorder	1	(0.0)
Lip swelling	1	(0.0)
Mouth ulceration	3	(0.0)
Nausea	168	(1.0)
Oral mucosal blistering	3	(0.0)
Oral pain	1	(0.0)
Paraesthesia oral	1	(0.0)
Stomatitis	1	(0.0)
Swollen tongue	2	(0.0)
Tongue disorder	1	(0.0)
Tongue pruritus	1	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Tongue ulceration	2	(0.0)
Toothache	1	(0.0)
Vomiting	33	(0.2)
Immune system disorder	9	(0.1)
Anaphylactic reaction	1	(0.0)
Hypersensitivity	3	(0.0)
Immunisation reaction	5	(0.0)
Injury, poisoning and procedural complications	3	(0.0)
Epicondylitis	1	(0.0)
Vaccination complication	2	(0.0)
General disorders and administration site conditions	4706	(28.8)
Administration site erythema	1	(0.0)
Administration site pain	5	(0.0)
Administration site reaction	2	(0.0)
Application site hyperaesthesia	1	(0.0)
Asthenia	68	(0.4)
Axillary pain	5	(0.0)
Chest discomfort	3	(0.0)
Chest pain	9	(0.1)
Chills	498	(3.1)
Discomfort	8	(0.1)
Face oedema	1	(0.0)
Facial pain	2	(0.0)
Fatigue	459	(2.8)
Feeling abnormal	9	(0.1)
Feeling cold	46	(0.3)
Feeling hot	44	(0.3)
Feeling of body temperature change	2	(0.0)
Gait disturbance	1	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
General physical health deterioration	1	(0.0)
Illness	4	(0.0)
Influenza like illness	93	(0.6)
Injection site atrophy	1	(0.0)
Injection site bruising	46	(0.3)
Injection site dermatitis	1	(0.0)
Injection site discomfort	23	(0.1)
Injection site eczema	4	(0.0)
Injection site erythema	1356	(8.3)
Injection site haematoma	14	(0.1)
Injection site haemorrhage	13	(0.1)
Injection site hyperaesthesia	2	(0.0)
Injection site hypersensitivity	5	(0.0)
Injection site hypoaesthesia	4	(0.0)
Injection site induration	59	(0.4)
Injection site inflammation	58	(0.4)
Injection site injury	1	(0.0)
Injection site irritation	4	(0.0)
Injection site joint pain	53	(0.3)
Injection site lymphadenopathy	2	(0.0)
Injection site macule	1	(0.0)
Injection site mass	11	(0.1)
Injection site movement impairment	9	(0.1)
General disorders and administration site conditions	4706	(28.8)
Injection site nodule	6	(0.0)
Injection site oedema	39	(0.2)
Injection site pain	3365	(20.6)
Injection site papule	1	(0.0)
Injection site paraesthesia	6	(0.0)
Injection site pruritus	325	(2.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Injection site rash	60	(0.4)
Injection site reaction	75	(0.5)
Injection site swelling	1014	(6.2)
Injection site ulcer	1	(0.0)
Injection site urticaria	7	(0.0)
Injection site vesicles	3	(0.0)
Injection site warmth	150	(0.9)
Malaise	238	(1.5)
Nodule	1	(0.0)
Oedema	2	(0.0)
Oedema peripheral	1	(0.0)
Pain	172	(1.1)
Peripheral swelling	5	(0.0)
Pyrexia	982	(6.0)
Sluggishness	1	(0.0)
Swelling	3	(0.0)
Temperature intolerance	1	(0.0)
Tenderness	2	(0.0)
Thirst	1	(0.0)
Vaccination site coldness	1	(0.0)
Vaccination site discolouration	1	(0.0)
Vaccination site erythema	37	(0.2)
Vaccination site inflammation	1	(0.0)
Vaccination site pain	63	(0.4)
Vaccination site pruritus	4	(0.0)
Vaccination site reaction	13	(0.1)
Vaccination site swelling	21	(0.1)
Vaccination site warmth	4	(0.0)
Metabolism and nutrition disorders	22	(0.1)
Decreased appetite	20	(0.1)
Dehydration	1	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Polydipsia	1	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(0.0)
Acrochordon	1	(0.0)
Infections and infestations	156	(1.0)
Bronchitis	1	(0.0)
Candida infection	1	(0.0)
Erysipelas	1	(0.0)
Gastroenteritis	3	(0.0)
Herpes simplex	4	(0.0)
Herpes zoster oticus	1	(0.0)
Influenza	20	(0.1)
Injection site cellulitis	4	(0.0)
Injection site infection	1	(0.0)
Lower respiratory tract infection	3	(0.0)
Nasopharyngitis	75	(0.5)
Oral candidiasis	1	(0.0)
Oral herpes	15	(0.1)
Pharyngitis	1	(0.0)
Respiratory tract infection	2	(0.0)
Respiratory tract infection viral	1	(0.0)
Rhinitis	3	(0.0)
Upper respiratory tract infection	16	(0.1)
Urinary tract infection	1	(0.0)
Viral infection	3	(0.0)
Viral rash	1	(0.0)
Investigations	111	(0.7)
Blood pressure increased	4	(0.0)
Body temperature decreased	1	(0.0)
Body temperature increased	104	(0.6)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
C-reactive protein increased	1	(0.0)
Grip strength decreased	1	(0.0)
Heart rate increased	2	(0.0)
Heart rate irregular	1	(0.0)
Musculoskeletal and connective tissue disorders	693	(4.2)
Arthralgia	160	(1.0)
Arthritis	1	(0.0)
Axillary mass	2	(0.0)
Back pain	47	(0.3)
Bone disorder	1	(0.0)
Bone pain	9	(0.1)
Bone swelling	1	(0.0)
Flank pain	1	(0.0)
Greater trochanteric pain syndrome	1	(0.0)
Joint stiffness	2	(0.0)
Joint swelling	2	(0.0)
Limb discomfort	3	(0.0)
Mobility decreased	1	(0.0)
Muscle discomfort	1	(0.0)
Muscle fatigue	2	(0.0)
Muscle rigidity	1	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Muscle spasms	8	(0.1)
Muscle tightness	2	(0.0)
Muscle twitching	1	(0.0)
Muscular weakness	8	(0.1)
Musculoskeletal chest pain	3	(0.0)
Musculoskeletal discomfort	1	(0.0)
Musculoskeletal pain	3	(0.0)
Musculoskeletal stiffness	14	(0.1)
Myalgia	432	(2.6)
Neck pain	27	(0.2)
Osteoarthritis	1	(0.0)
Pain in extremity	52	(0.3)
Pain in jaw	1	(0.0)
Rheumatoid arthritis	2	(0.0)
Synovitis	1	(0.0)
Torticollis	1	(0.0)
Renal and urinary disorders	8	(0.1)
Dysuria	1	(0.0)
Pollakiuria	5	(0.0)
Polyuria	1	(0.0)
Urinary incontinence	1	(0.0)
Nervous system disorder	891	(5.5)
Balance disorder	6	(0.0)
Burning sensation	2	(0.0)
Carpal tunnel syndrome	1	(0.0)
Cerebral ischaemia	1	(0.0)
Disturbance in attention	2	(0.0)
Dizziness	112	(0.7)
Dizziness postural	1	(0.0)
Dysgeusia	5	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Head discomfort	7	(0.0)
Headache	729	(4.5)
Hyperaesthesia	3	(0.0)
Hypersomnia	4	(0.0)
Hypoaesthesia	7	(0.0)
Hypotonia	1	(0.0)
Lethargy	27	(0.2)
Migraine	5	(0.0)
Muscle contractions involuntary	1	(0.0)
Paraesthesia	7	(0.0)
Presyncope	2	(0.0)
Restless legs syndrome	2	(0.0)
Somnolence	28	(0.2)
Syncope	6	(0.0)
Taste disorder	1	(0.0)
Tension headache	2	(0.0)
Tremor	4	(0.0)
Trigeminal neuralgia	1	(0.0)
Mental disorder	57	(0.4)
Anxiety	5	(0.0)
Aversion	1	(0.0)
Depressed mood	3	(0.0)
Disorientation	2	(0.0)
Dysphoria	1	(0.0)
Emotional disorder	1	(0.0)
Hallucination	1	(0.0)
Insomnia	30	(0.2)
Irritability	1	(0.0)
Libido decreased	1	(0.0)
Listless	1	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Middle insomnia	1	(0.0)
Mood altered	1	(0.0)
Nightmare	1	(0.0)
Mental disorder	57	(0.4)
Poor quality sleep	2	(0.0)
Restlessness	6	(0.0)
Sleep disorder	2	(0.0)
Reproductive system and breast disorders	5	(0.0)
Breast pain	2	(0.0)
Erectile dysfunction	2	(0.0)
Pelvic pain	1	(0.0)
Respiratory, thoracic and mediastinal disorders	77	(0.5)
Cough	19	(0.1)
Dry throat	1	(0.0)
Dyspnoea	6	(0.0)
Lower respiratory tract congestion	1	(0.0)
Nasal congestion	4	(0.0)
Oropharyngeal discomfort	1	(0.0)
Oropharyngeal pain	37	(0.2)
Paranasal sinus discomfort	1	(0.0)
Respiratory tract congestion	1	(0.0)
Rhinorrhoea	14	(0.1)
Sneezing	1	(0.0)
Throat irritation	2	(0.0)
Upper respiratory tract inflammation	1	(0.0)
Vasomotor rhinitis	1	(0.0)
Wheezing	1	(0.0)
Surgical and medical procedures	1	(0.0)
Tooth extraction	1	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Angiopathy	25	(0.2)
Angiopathy	1	(0.0)
Blood pressure fluctuation	2	(0.0)
Flushing	8	(0.1)
Hot flush	6	(0.0)
Hyperaemia	1	(0.0)
Hypertension	2	(0.0)
Hypotension	2	(0.0)
Peripheral coldness	2	(0.0)
Varicose vein	1	(0.0)
Skin and subcutaneous tissue disorders	168	(1.0)
Alopecia areata	1	(0.0)
Blister	1	(0.0)
Cold sweat	6	(0.0)
Cutaneous vasculitis	1	(0.0)
Dermatitis contact	1	(0.0)
Dermatitis exfoliative generalised	1	(0.0)
Ecchymosis	1	(0.0)
Eczema	5	(0.0)
Erythema	31	(0.2)
Hyperhidrosis	25	(0.2)
Hypohidrosis	3	(0.0)
Night sweats	1	(0.0)
Onychalgia	1	(0.0)
Pain of skin	2	(0.0)
Papule	2	(0.0)
Photosensitivity reaction	1	(0.0)
Pruritus	51	(0.3)
Psoriasis	3	(0.0)
Rash	31	(0.2)
Rash macular	3	(0.0)

Attached Form 2-2 The occurrence of unsolicited ADRs in Phase III studies

< Unsolicited ADRs >

The name of studies: ZOSTER-002, ZOSTER-028, ZOSTER-039, ZOSTER-041, ZOSTER-006, ZOSTER-022, ZOSTER-026

	Status of phase III studies	
Number of subjects included in safety analysis	16337	
Number of subjects with ADRs	5133	
Incidence proportion of ADRs	31.4%	
Type of ADR	Number of subjects with ADRs by type (incidence proportion)	
Rash pruritic	3	(0.0)
Skin burning sensation	1	(0.0)
Skin exfoliation	1	(0.0)
Skin swelling	1	(0.0)
Skin warm	2	(0.0)
Urticaria	4	(0.0)

MedDRA/J version 25.1

Table 8-1 Incidence of ADRs by seriousness (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total**	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	7707					
Number of doses with ADRs	6137	0	542	1	6158	1
Incidence proportion of ADRs (%)	79.6	0.0	7.0	0.0	79.9	0.0
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
General disorders and administration site conditions	6084 (78.9)	0 (0.0)	249 (3.2)	0 (0.0)	6095 (79.1)	0 (0.0)
Vaccination site pain	5709 (74.1)	0 (0.0)	6 (0.1)	0 (0.0)	5716 (74.2)	0 (0.0)
Vaccination site swelling	3269 (42.4)	0 (0.0)	4 (0.1)	0 (0.0)	3274 (42.5)	0 (0.0)
Vaccination site erythema	3132 (40.6)	0 (0.0)	3 (0.0)	0 (0.0)	3136 (40.7)	0 (0.0)
Fatigue	2318 (30.1)	0 (0.0)	5 (0.1)	0 (0.0)	2324 (30.2)	0 (0.0)
Pyrexia	2132 (27.7)	0 (0.0)	3 (0.0)	0 (0.0)	2135 (27.7)	0 (0.0)
Chills	791 (10.3)	0 (0.0)	3 (0.0)	0 (0.0)	795 (10.3)	0 (0.0)
Vaccination site pruritus	0 (0.0)	0 (0.0)	155 (2.0)	0 (0.0)	155 (2.0)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	29 (0.4)	0 (0.0)	29 (0.4)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)	8 (0.1)	0 (0.0)
Swelling	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Feeling abnormal	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Peripheral swelling	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Asthenia	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site induration	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Condition aggravated	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Mass	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injected limb mobility decreased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site reaction	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site mass	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	2324 (30.2)	0 (0.0)	101 (1.3)	0 (0.0)	2357 (30.6)	0 (0.0)
Myalgia	2324 (30.2)	0 (0.0)	4 (0.1)	0 (0.0)	2328 (30.2)	0 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	52 (0.7)	0 (0.0)	52 (0.7)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	19 (0.2)	0 (0.0)	19 (0.2)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Neck pain	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nervous system disorders	1730 (22.4)	0 (0.0)	68 (0.9)	0 (0.0)	1762 (22.9)	0 (0.0)
Headache	1730 (22.4)	0 (0.0)	6 (0.1)	0 (0.0)	1736 (22.5)	0 (0.0)
Dizziness	0 (0.0)	0 (0.0)	24 (0.3)	0 (0.0)	24 (0.3)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Hypoesthesia	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Parosmia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tremor	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 8-1 Incidence of ADRs by seriousness (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total**	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	7707					
Number of doses with ADRs	6137	0	542	1	6158	1
Incidence proportion of ADRs (%)	79.6	0.0	7.0	0.0	79.9	0.0
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
Gastrointestinal disorders	478 (6.2)	0 (0.0)	40 (0.5)	0 (0.0)	505 (6.6)	0 (0.0)
Diarrhoea	234 (3.0)	0 (0.0)	3 (0.0)	0 (0.0)	236 (3.1)	0 (0.0)
Nausea	224 (2.9)	0 (0.0)	3 (0.0)	0 (0.0)	227 (2.9)	0 (0.0)
Abdominal pain	160 (2.1)	0 (0.0)	2 (0.0)	0 (0.0)	162 (2.1)	0 (0.0)
Vomiting	54 (0.7)	0 (0.0)	1 (0.0)	0 (0.0)	55 (0.7)	0 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypoesthesia oral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	115 (1.5)	0 (0.0)	115 (1.5)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	73 (0.9)	0 (0.0)	73 (0.9)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	19 (0.2)	0 (0.0)	19 (0.2)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)	11 (0.1)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)	8 (0.1)	0 (0.0)
Blister	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Purpura	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	30 (0.4)	0 (0.0)	30 (0.4)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	18 (0.2)	0 (0.0)	18 (0.2)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	13 (0.2)	0 (0.0)	13 (0.2)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	15 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	12 (0.2)	1 (0.0)	12 (0.2)	1 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Infections and infestations	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye disorders	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 8-1 Incidence of ADRs by seriousness (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total**	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	7707					
Number of doses with ADRs	6137	0	542	1	6158	1
Incidence proportion of ADRs (%)	79.6	0.0	7.0	0.0	79.9	0.0
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
Investigations	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

*The following adverse drug reactions occurred within 7 days after Shingrix vaccination (up to Day 7 when the day of vaccination defined as Day 1)

MedDRA/J (28.0)

Local: injection site pain, injection site redness, and injection site swelling

Systemic: myalgia, fatigue, headache, chills, pyrexia, and gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain)

**Counted as 1 if the subject experienced both solicited and unsolicited events

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Table 8-2 Incidence of ADRs by severity (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination	Solicited adverse events					Unsolicited adverse events					Combined*, **				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	7707					7707					7707				
Number of doses with ADRs (solicited/unsolicited)	6137					542					6158				
Number of doses with ADRs	48	3515	2023	504	47	0	407	103	20	12	46	3515	2043	509	45
Incidence proportion of ADRs (%)	0.6	45.6	26.2	6.5	0.6	0.0	5.3	1.3	0.3	0.2	0.6	45.6	26.5	6.6	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
Infections and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	4 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	4 (0.1)	4 (0.1)	1 (0.0)	1 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.2)	6 (0.1)	0 (0.0)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	2 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	10 (0.1)	2 (0.0)	1 (0.0)	2 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	2 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	10 (0.1)	2 (0.0)	1 (0.0)	2 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nervous system disorders	1 (0.0)	1309 (17.0)	340 (4.4)	53 (0.7)	27 (0.4)	0 (0.0)	45 (0.6)	17 (0.2)	3 (0.0)	3 (0.0)	1 (0.0)	1324 (17.2)	353 (4.6)	56 (0.7)	28 (0.4)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.2)	8 (0.1)	2 (0.0)	1 (0.0)	0 (0.0)	13 (0.2)	8 (0.1)	2 (0.0)	1 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Headache	1 (0.0)	1309 (17.0)	340 (4.4)	53 (0.7)	27 (0.4)	0 (0.0)	4 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1313 (17.0)	341 (4.4)	54 (0.7)	27 (0.4)
Hypoesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)
Parosmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Parosmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	3 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	10 (0.1)	3 (0.0)	0 (0.0)	2 (0.0)
Tremor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)

Table 8-2 Incidence of ADRs by severity (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination	Solicited adverse events					Unsolicited adverse events					Combined*, **				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	7707					7707					7707				
Number of doses with ADRs (solicited/unsolicited)	6137					542					6158				
Number of doses with ADRs	48	3515	2023	504	47	0	407	103	20	12	46	3515	2043	509	45
Incidence proportion of ADRs (%)	0.6	45.6	26.2	6.5	0.6	0.0	5.3	1.3	0.3	0.2	0.6	45.6	26.5	6.6	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	25 (0.3)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	25 (0.3)	4 (0.1)	1 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	393 (5.1)	67 (0.9)	12 (0.2)	6 (0.1)	0 (0.0)	32 (0.4)	8 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	412 (5.3)	75 (1.0)	12 (0.2)	6 (0.1)
Abdominal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain	0 (0.0)	131 (1.7)	19 (0.2)	3 (0.0)	7 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	133 (1.7)	19 (0.2)	3 (0.0)	7 (0.1)
Abdominal pain upper	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	0 (0.0)	202 (2.6)	27 (0.4)	3 (0.0)	2 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	204 (2.6)	27 (0.4)	3 (0.0)	2 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	0 (0.0)	179 (2.3)	32 (0.4)	8 (0.1)	5 (0.1)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	181 (2.3)	33 (0.4)	8 (0.1)	5 (0.1)
Oral discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vomiting	0 (0.0)	38 (0.5)	11 (0.1)	3 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	38 (0.5)	12 (0.2)	3 (0.0)	2 (0.0)
Hypoaesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 8-2 Incidence of ADRs by severity (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination

	Solicited adverse events					Unsolicited adverse events					Combined*, **				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	7707					7707					7707				
Number of doses with ADRs (solicited/unsolicited)	6137					542					6158				
Number of doses with ADRs	48	3515	2023	504	47	0	407	103	20	12	46	3515	2043	509	45
Incidence proportion of ADRs (%)	0.6	45.6	26.2	6.5	0.6	0.0	5.3	1.3	0.3	0.2	0.6	45.6	26.5	6.6	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	100 (1.5)	10 (0.1)	1 (0.0)	4 (0.1)	0 (0.0)	100 (1.5)	10 (0.1)	1 (0.0)	4 (0.1)
Blisters	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	65 (0.9)	6 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	65 (0.9)	6 (0.1)	1 (0.0)	1 (0.0)
Purpura	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	3 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	14 (0.2)	3 (0.0)	0 (0.0)	2 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	1 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	2 (0.0)	1830 (23.7)	378 (4.9)	69 (0.9)	45 (0.6)	0 (0.0)	57 (0.7)	34 (0.4)	9 (0.1)	1 (0.0)	2 (0.0)	1844 (23.9)	394 (5.1)	72 (0.9)	45 (0.6)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	28 (0.4)	17 (0.2)	6 (0.1)	1 (0.0)	0 (0.0)	28 (0.4)	17 (0.2)	6 (0.1)	1 (0.0)
Back pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	9 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	9 (0.1)	0 (0.0)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)
Myalgia	2 (0.0)	1830 (23.7)	378 (4.9)	69 (0.9)	45 (0.6)	0 (0.0)	2 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	1832 (23.8)	379 (4.9)	70 (0.9)	45 (0.6)
Neck pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Poliakuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)

Table 8-2 Incidence of ADRs by severity (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination	Solicited adverse events					Unsolicited adverse events					Combined*, **				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	7707					7707					7707				
Number of doses with ADRs (solicited/unsolicited)	6137					542					6158				
Number of doses with ADRs	48	3515	2023	504	47	0	407	103	20	12	46	3515	2043	509	45
Incidence proportion of ADRs (%)	0.6	45.6	26.2	6.5	0.6	0.0	5.3	1.3	0.3	0.2	0.6	45.6	26.5	6.6	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
General disorders and administration site conditions	62 (0.8)	3563 (46.2)	1936 (25.1)	475 (6.2)	48 (0.6)	0 (0.0)	204 (2.6)	36 (0.5)	5 (0.1)	4 (0.1)	62 (0.8)	3562 (46.2)	1947 (25.3)	477 (6.2)	47 (0.6)
Asthma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Chills	0 (0.0)	575 (7.5)	160 (2.1)	48 (0.6)	8 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	578 (7.5)	160 (2.1)	49 (0.6)	8 (0.1)
Condition aggravated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Fatigue	1 (0.0)	1698 (22.0)	482 (6.3)	100 (1.3)	37 (0.5)	0 (0.0)	4 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1703 (22.1)	482 (6.3)	101 (1.3)	37 (0.5)
Feeling abnormal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	13 (0.2)	2 (0.0)	0 (0.0)	0 (0.0)	14 (0.2)	13 (0.2)	2 (0.0)	0 (0.0)
Mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	4 (0.1)	0 (0.0)	0 (0.0)
Pyrexia	674 (8.7)	1021 (13.2)	383 (5.0)	28 (0.4)	26 (0.3)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	674 (8.7)	1023 (13.3)	384 (5.0)	28 (0.4)	26 (0.3)
Swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Peripheral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Injected limb mobility decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vaccination site erythema	536 (7.0)	1363 (17.7)	936 (12.1)	237 (3.1)	60 (0.8)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	536 (7.0)	1366 (17.7)	937 (12.2)	237 (3.1)	60 (0.8)
Vaccination site reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site pain	2 (0.0)	4602 (59.7)	889 (11.5)	118 (1.5)	98 (1.3)	0 (0.0)	5 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	4608 (59.8)	889 (11.5)	119 (1.5)	98 (1.3)
Vaccination site pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	143 (1.9)	9 (0.1)	0 (0.0)	3 (0.0)	0 (0.0)	143 (1.9)	9 (0.1)	0 (0.0)	3 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site swelling	598 (7.8)	1617 (21.0)	805 (10.4)	182 (2.4)	67 (0.9)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	598 (7.8)	1620 (21.0)	807 (10.5)	182 (2.4)	67 (0.9)
Vaccination site warmth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	0 (0.0)	1 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vaccination site mass	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Investigations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

*If there are multiple events with the same SOC and PT in the same subject, the events will be adopted based on the following priority: Grade 3 > 2 > 1 > 0 > Unknown.

**Counted as 1 if the subject experienced both solicited and unsolicited events.

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

MedDRA J (28.0)

Table 8-3 Incidence of ADRs by seriousness (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total**	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	7464					
Number of doses with ADRs	5559	0	369	4	5574	4
Incidence proportion of ADRs (%)	74.5	0.0	4.9	0.1	74.7	0.1
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
General disorders and administration site conditions	5528 (74.1)	0 (0.0)	173 (2.3)	0 (0.0)	5542 (74.2)	0 (0.0)
Vaccination site pain	5078 (68.0)	0 (0.0)	10 (0.1)	0 (0.0)	5088 (68.2)	0 (0.0)
Vaccination site swelling	3291 (44.1)	0 (0.0)	7 (0.1)	0 (0.0)	3298 (44.2)	0 (0.0)
Vaccination site erythema	3099 (41.5)	0 (0.0)	10 (0.1)	0 (0.0)	3109 (41.7)	0 (0.0)
Pyrexia	2373 (31.8)	0 (0.0)	5 (0.1)	0 (0.0)	2378 (31.9)	0 (0.0)
Fatigue	2218 (29.7)	0 (0.0)	9 (0.1)	0 (0.0)	2227 (29.8)	0 (0.0)
Chills	941 (12.6)	0 (0.0)	3 (0.0)	0 (0.0)	944 (12.6)	0 (0.0)
Vaccination site pruritus	0 (0.0)	0 (0.0)	111 (1.5)	0 (0.0)	111 (1.5)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	20 (0.3)	0 (0.0)	20 (0.3)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Feeling abnormal	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Asthenia	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Feeling cold	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Facial pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injection site paraesthesia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	2129 (28.5)	0 (0.0)	83 (1.1)	1 (0.0)	2163 (29.0)	1 (0.0)
Myalgia	2129 (28.5)	0 (0.0)	6 (0.1)	0 (0.0)	2134 (28.6)	0 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	41 (0.5)	0 (0.0)	41 (0.5)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	20 (0.3)	0 (0.0)	20 (0.3)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Neck pain	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nervous system disorders	1806 (24.2)	0 (0.0)	43 (0.6)	0 (0.0)	1829 (24.5)	0 (0.0)
Headache	1806 (24.2)	0 (0.0)	5 (0.1)	0 (0.0)	1811 (24.3)	0 (0.0)
Dizziness	0 (0.0)	0 (0.0)	13 (0.2)	0 (0.0)	13 (0.2)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)	8 (0.1)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Hypoaesthesia	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 8-3 Incidence of ADRs by seriousness (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total**	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	7464					
Number of doses with ADRs	5559	0	369	4	5574	4
Incidence proportion of ADRs (%)	74.5	0.0	4.9	0.1	74.7	0.1
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
Gastrointestinal disorders	387 (5.2)	0 (0.0)	29 (0.4)	1 (0.0)	406 (5.4)	1 (0.0)
Nausea	205 (2.7)	0 (0.0)	1 (0.0)	0 (0.0)	206 (2.8)	0 (0.0)
Diarrhoea	158 (2.1)	0 (0.0)	5 (0.1)	0 (0.0)	163 (2.2)	0 (0.0)
Abdominal pain	154 (2.1)	0 (0.0)	2 (0.0)	0 (0.0)	156 (2.1)	0 (0.0)
Vomiting	34 (0.5)	0 (0.0)	2 (0.0)	0 (0.0)	36 (0.5)	0 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gingival pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Melaena	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Oral pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip blister	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	62 (0.8)	0 (0.0)	62 (0.8)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	44 (0.6)	0 (0.0)	44 (0.6)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	12 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)	8 (0.1)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)

Table 8-3 Incidence of ADRs by seriousness (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total**	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	7464					
Number of doses with ADRs	5559	0	369	4	5574	4
Incidence proportion of ADRs (%)	74.5	0.0	4.9	0.1	74.7	0.1
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
Eye disorders	0 (0.0)	0 (0.0)	7 (0.1)	1 (0.0)	7 (0.1)	1 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Hypoacusis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	4 (0.1)	1 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Listless	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Infections and infestations	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Investigations	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

*The following adverse drug reactions occurred within 7 days after Shingrix vaccination (up to Day 7 when the day of vaccination defined as Day 1)

MedDRA/J (28.0)

Local: injection site pain, injection site redness, and injection site swelling

Systemic: myalgia, fatigue, headache, chills, pyrexia, and gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain)

**Counted as 1 if the subject experienced both solicited and unsolicited events

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Table 8-4 Incidence of ADRs by severity (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

	Solicited adverse events						Unsolicited adverse events						Combined*, **					
	Severity						Severity						Severity					
	0	1	2	3	Unknown		0	1	2	3	Unknown		0	1	2	3	Unknown	
Number of doses	7464						7464						7464					
Number of doses with ADRs (solicited/unsolicited)	5559						369						5574					
Number of doses with ADRs	73	3075	1810	554	47		1	268	78	15	7		72	3074	1821	560	47	
Cumulative incidence of ADRs (%)	1.0	41.2	24.2	7.4	0.6		0.0	3.6	1.0	0.2	0.1		1.0	41.2	24.4	7.5	0.6	
Type of ADR	Number of doses with ADRs (%)						Number of doses with ADRs (%)						Number of doses with ADRs (%)					
Infections and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Postale	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Listless	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Nervous system disorders	0 (0.0)	1297 (17.4)	399 (5.3)	65 (0.9)	45 (0.6)	0 (0.0)	0 (0.0)	27 (0.4)	14 (0.2)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1308 (17.5)	410 (5.5)	66 (0.9)	45 (0.6)	0 (0.0)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Headache	0 (0.0)	1297 (17.4)	399 (5.3)	65 (0.9)	45 (0.6)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1302 (17.4)	399 (5.3)	65 (0.9)	45 (0.6)	0 (0.0)
Hypoesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	5 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	5 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	3 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	3 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 8-4 Incidence of ADRs by severity (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

	Solicited adverse events						Unsolicited adverse events						Combined*, **					
	Severity						Severity						Severity					
	0	1	2	3	Unknown		0	1	2	3	Unknown		0	1	2	3	Unknown	
Number of doses	7464						7464						7464					
Number of doses with ADRs (solicited/unsolicited)	5559						369						5574					
Number of doses with ADRs	73	3075	1810	554	47		1	268	78	15	7		72	3074	1821	560	47	
Cumulative incidence of ADRs (%)	1.0	41.2	24.2	7.4	0.6		0.0	3.6	1.0	0.2	0.1		1.0	41.2	24.4	7.5	0.6	
Type of ADR	Number of doses with ADRs (%)						Number of doses with ADRs (%)						Number of doses with ADRs (%)					
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	296 (4.0)	71 (1.0)	15 (0.2)	5 (0.1)	0 (0.0)	0 (0.0)	20 (0.3)	4 (0.1)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	310 (4.2)	73 (1.0)	17 (0.2)	6 (0.1)	0 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain	0 (0.0)	123 (1.6)	27 (0.4)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	123 (1.6)	28 (0.4)	3 (0.0)	2 (0.0)	0 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	0 (0.0)	129 (1.7)	22 (0.3)	4 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	133 (1.8)	22 (0.3)	5 (0.1)	3 (0.0)	0 (0.0)
Gingival pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Melena	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	0 (0.0)	151 (2.0)	42 (0.6)	9 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	151 (2.0)	42 (0.6)	9 (0.1)	4 (0.1)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting	0 (0.0)	14 (0.2)	12 (0.2)	5 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	14 (0.2)	12 (0.2)	6 (0.1)	4 (0.1)	0 (0.0)
Lip blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parosmia/oral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	52 (0.7)	9 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	52 (0.7)	9 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	36 (0.5)	7 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	36 (0.5)	7 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 8-4 Incidence of ADRs by severity (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination

	Solicited adverse events					Unsolicited adverse events					Combined*, **				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	7464					7464					7464				
Number of doses with ADRs (solicited/unsolicited)	5559					369					5554				
Number of doses with ADRs	73	3075	1810	554	47	1	268	78	15	7	72	3074	1821	560	47
Cumulative incidence of ADRs (%)	1.0	41.2	24.2	7.4	0.6	0.0	3.6	1.0	0.2	0.1	1.0	41.2	24.4	7.5	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
Musculoskeletal and connective tissue disorders	1 (0.0)	1636 (21.9)	380 (5.1)	63 (0.8)	49 (0.7)	0 (0.0)	48 (0.6)	28 (0.4)	6 (0.1)	1 (0.0)	1 (0.0)	1652 (22.1)	395 (5.3)	67 (0.9)	48 (0.6)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	26 (0.3)	12 (0.2)	3 (0.0)	0 (0.0)	0 (0.0)	26 (0.3)	12 (0.2)	3 (0.0)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	9 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	9 (0.1)	1 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Myalgia	1 (0.0)	1636 (21.9)	380 (5.1)	63 (0.8)	49 (0.7)	0 (0.0)	5 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1640 (22.0)	380 (5.1)	64 (0.9)	49 (0.7)
Neck pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	3 (0.0)	1 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Urinary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
General disorders and administration site conditions	82 (1.1)	3128 (41.9)	1747 (23.4)	524 (7.0)	47 (0.6)	1 (0.0)	145 (1.9)	22 (0.3)	2 (0.0)	3 (0.0)	80 (1.1)	3137 (42.0)	1752 (23.5)	526 (7.0)	47 (0.6)
Asthenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Chills	0 (0.0)	623 (8.3)	234 (3.1)	66 (0.9)	18 (0.2)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	626 (8.4)	234 (3.1)	66 (0.9)	18 (0.2)
Discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Facial pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue	1 (0.0)	1506 (20.2)	547 (7.3)	107 (1.4)	57 (0.8)	0 (0.0)	9 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1515 (20.3)	547 (7.3)	107 (1.4)	57 (0.8)
Feeling abnormal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling cold	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Injection site paraesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.2)	5 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	13 (0.2)	5 (0.1)	1 (0.0)	1 (0.0)
Pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)
Pyrexia	620 (8.3)	1170 (15.7)	521 (7.0)	40 (0.5)	22 (0.3)	3 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	623 (8.3)	1172 (15.7)	521 (7.0)	40 (0.5)	22 (0.3)
Thirst	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vaccination site erythema	526 (7.0)	1389 (18.6)	840 (11.3)	281 (3.8)	63 (0.8)	1 (0.0)	6 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	527 (7.1)	1395 (18.7)	843 (11.3)	281 (3.8)	63 (0.8)
Vaccination site pain	1 (0.0)	4149 (55.6)	728 (9.8)	101 (1.4)	99 (1.3)	0 (0.0)	10 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	4159 (55.7)	728 (9.8)	101 (1.4)	99 (1.3)
Vaccination site pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	103 (1.4)	7 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	103 (1.4)	7 (0.1)	0 (0.0)	1 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site swelling	600 (8.0)	1627 (21.8)	761 (10.2)	231 (3.1)	72 (1.0)	0 (0.0)	4 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	600 (8.0)	1631 (21.9)	764 (10.2)	231 (3.1)	72 (1.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Investigations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

*If there are multiple events with the same SOC and PT in the same subject, the events will be adopted based on the following priority: Grade 3 > 2 > 1 > 0 > Unknown.

**Counted as 1 if the subject experienced both solicited and unsolicited events

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

MedDRA J (28.0)

Table 8-5 Incidence of ADRs by seriousness (Cumulative vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	15171					
Number of doses with ADRs	11696	0	911	5	11732	5
Incidence proportion of ADRs (%)	77.1	0.0	6.0	0.0	77.3	0.0
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
General disorders and administration site conditions	11612 (76.5)	0 (0.0)	422 (2.8)	0 (0.0)	11637 (76.7)	0 (0.0)
Vaccination site pain	10787 (71.1)	0 (0.0)	16 (0.1)	0 (0.0)	10804 (71.2)	0 (0.0)
Vaccination site swelling	6560 (43.2)	0 (0.0)	11 (0.1)	0 (0.0)	6572 (43.3)	0 (0.0)
Vaccination site erythema	6231 (41.1)	0 (0.0)	13 (0.1)	0 (0.0)	6245 (41.2)	0 (0.0)
Fatigue	4536 (29.9)	0 (0.0)	14 (0.1)	0 (0.0)	4551 (30.0)	0 (0.0)
Pyrexia	4505 (29.7)	0 (0.0)	8 (0.1)	0 (0.0)	4513 (29.7)	0 (0.0)
Chills	1732 (11.4)	0 (0.0)	6 (0.0)	0 (0.0)	1739 (11.5)	0 (0.0)
Vaccination site pruritus	0 (0.0)	0 (0.0)	266 (1.8)	0 (0.0)	266 (1.8)	0 (0.0)
Malaise	0 (0.0)	0 (0.0)	49 (0.3)	0 (0.0)	49 (0.3)	0 (0.0)
Vaccination site warmth	0 (0.0)	0 (0.0)	15 (0.1)	0 (0.0)	15 (0.1)	0 (0.0)
Chest pain	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	13 (0.1)	0 (0.0)
Pain	0 (0.0)	0 (0.0)	12 (0.1)	0 (0.0)	12 (0.1)	0 (0.0)
Axillary pain	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)	11 (0.1)	0 (0.0)
Feeling abnormal	0 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)
Swelling	0 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)
Feeling hot	0 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)
Thirst	0 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)
Asthenia	0 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)
Peripheral swelling	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)
Oedema peripheral	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site induration	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Vaccination site discolouration	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Condition aggravated	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Feeling cold	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site bruising	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Facial pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injection site paraesthesia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Mass	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injected limb mobility decreased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site reaction	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site mass	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	4453 (29.4)	0 (0.0)	184 (1.2)	1 (0.0)	4520 (29.8)	1 (0.0)
Myalgia	4453 (29.4)	0 (0.0)	10 (0.1)	0 (0.0)	4462 (29.4)	0 (0.0)
Arthralgia	0 (0.0)	0 (0.0)	93 (0.6)	0 (0.0)	93 (0.6)	0 (0.0)
Back pain	0 (0.0)	0 (0.0)	39 (0.3)	0 (0.0)	39 (0.3)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	16 (0.1)	0 (0.0)	16 (0.1)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	15 (0.1)	0 (0.0)	15 (0.1)	0 (0.0)
Neck pain	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)

Table 8-5 Incidence of ADRs by seriousness (Cumulative vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	15171					
Number of doses with ADRs	11696	0	911	5	11732	5
Incidence proportion of ADRs (%)	77.1	0.0	6.0	0.0	77.3	0.0
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
Nervous system disorders	3536 (23.3)	0 (0.0)	111 (0.7)	0 (0.0)	3591 (23.7)	0 (0.0)
Headache	3536 (23.3)	0 (0.0)	11 (0.1)	0 (0.0)	3547 (23.4)	0 (0.0)
Dizziness	0 (0.0)	0 (0.0)	37 (0.2)	0 (0.0)	37 (0.2)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	23 (0.2)	0 (0.0)	23 (0.2)	0 (0.0)
Hypoaesthesia	0 (0.0)	0 (0.0)	11 (0.1)	0 (0.0)	11 (0.1)	0 (0.0)
Paraesthesia	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Parosmia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tremor	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastrointestinal disorders	865 (5.7)	0 (0.0)	69 (0.5)	1 (0.0)	911 (6.0)	1 (0.0)
Nausea	429 (2.8)	0 (0.0)	4 (0.0)	0 (0.0)	433 (2.9)	0 (0.0)
Diarrhoea	392 (2.6)	0 (0.0)	8 (0.1)	0 (0.0)	399 (2.6)	0 (0.0)
Abdominal pain	314 (2.1)	0 (0.0)	4 (0.0)	0 (0.0)	318 (2.1)	0 (0.0)
Vomiting	88 (0.6)	0 (0.0)	3 (0.0)	0 (0.0)	91 (0.6)	0 (0.0)
Abdominal pain upper	0 (0.0)	0 (0.0)	12 (0.1)	0 (0.0)	12 (0.1)	0 (0.0)
Stomatitis	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Abdominal discomfort	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Toothache	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Oral pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Salivary gland pain	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Paraesthesia oral	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Cheilitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gingival pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Glossodynia	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Melaena	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Oral discomfort	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue rough	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Lip blister	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypoaesthesia oral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Tongue exfoliation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosa erosion	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Loose tooth	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Faeces soft	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Anal incontinence	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oral mucosal roughening	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 8-5 Incidence of ADRs by seriousness (Cumulative vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	15171					
Number of doses with ADRs	11696	0	911	5	11732	5
Incidence proportion of ADRs (%)	77.1	0.0	6.0	0.0	77.3	0.0
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	177 (1.2)	0 (0.0)	177 (1.2)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	117 (0.8)	0 (0.0)	117 (0.8)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	21 (0.1)	0 (0.0)	21 (0.1)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	16 (0.1)	0 (0.0)	16 (0.1)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	12 (0.1)	0 (0.0)	12 (0.1)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Blister	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Purpura	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	39 (0.3)	0 (0.0)	39 (0.3)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	13 (0.1)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	10 (0.1)	0 (0.0)	10 (0.1)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	27 (0.2)	0 (0.0)	27 (0.2)	0 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	27 (0.2)	0 (0.0)	27 (0.2)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	25 (0.2)	0 (0.0)	25 (0.2)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	19 (0.1)	0 (0.0)	19 (0.1)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)	8 (0.1)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	18 (0.1)	0 (0.0)	18 (0.1)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)	5 (0.0)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Hypoacusis	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	15 (0.1)	1 (0.0)	15 (0.1)	1 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)

Table 8-5 Incidence of ADRs by seriousness (Cumulative vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events*		Unsolicited adverse events		Combined total	
	Total	Serious	Total	Serious	Total	Serious
Number of doses	15171					
Number of doses with ADRs	11696	0	911	5	11732	5
Incidence proportion of ADRs (%)	77.1	0.0	6.0	0.0	77.3	0.0
Type of ADR	Number of doses with ADRs (%)		Number of doses with ADRs (%)		Number of doses with ADRs (%)	
Eye disorders	0 (0.0)	0 (0.0)	14 (0.1)	1 (0.0)	14 (0.1)	1 (0.0)
Eye pain	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Infections and infestations	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	13 (0.1)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	13 (0.1)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	13 (0.1)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	13 (0.1)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)	6 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Investigations	0 (0.0)	0 (0.0)	8 (0.1)	0 (0.0)	8 (0.1)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	5 (0.0)	1 (0.0)	5 (0.0)	1 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Listless	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

*The following adverse drug reactions occurred within 7 days after Shingrix vaccination (up to Day 7 when the day of vaccination defined as Day 1)

MedDRA/J (28.0)

Local: injection site pain, injection site redness, and injection site swelling

Systemic: myalgia, fatigue, headache, chills, pyrexia, and gastrointestinal symptoms (nausea, vomiting, diarrhoea, abdominal pain)

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Table 8-6 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events					Unsolicited adverse events					Combined*				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	15771					15771					15771				
Number of doses with ADRs (solicited/unsolicited)	11696					911					11732				
Number of doses with ADRs	121	6590	3833	1058	94	1	675	181	35	19	118	6589	3864	1069	92
Incidence proportion of ADRs (%)	0.8	43.4	25.3	7.0	0.6	0.0	4.4	1.2	0.2	0.1	0.8	43.4	25.5	7.0	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
Infections and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.0)	5 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	6 (0.0)	5 (0.0)	1 (0.0)	1 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (0.1)	7 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (0.1)	7 (0.0)	0 (0.0)	0 (0.0)
Lymph node pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)
Lymphadenopathy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (0.1)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (0.1)	4 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	19 (0.1)	5 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	19 (0.1)	5 (0.0)	1 (0.0)	2 (0.0)
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	19 (0.1)	5 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	19 (0.1)	5 (0.0)	1 (0.0)	2 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Listless	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nervous system disorders	1 (0.0)	2606 (17.2)	739 (4.9)	118 (0.8)	72 (0.5)	0 (0.0)	72 (0.5)	31 (0.2)	5 (0.0)	3 (0.0)	1 (0.0)	2632 (17.3)	763 (5.0)	122 (0.8)	73 (0.5)
Dizziness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	22 (0.1)	11 (0.1)	3 (0.0)	1 (0.0)	0 (0.0)	22 (0.1)	11 (0.1)	3 (0.0)	1 (0.0)
Dizziness postural	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysaesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Headache	1 (0.0)	2606 (17.2)	739 (4.9)	118 (0.8)	72 (0.5)	0 (0.0)	9 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	2615 (17.2)	740 (4.9)	119 (0.8)	72 (0.5)
Hypoesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Migraine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)
Paresthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)
Parosmia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peroneal nerve palsy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Somnolence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.1)	8 (0.1)	1 (0.0)	2 (0.0)	0 (0.0)	12 (0.1)	8 (0.1)	1 (0.0)	2 (0.0)
Tremor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Balance disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)
Taste disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Brain fog	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)

Table 8-6 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events					Unsolicited adverse events					Combined*				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	15771					15771					15771				
Number of doses with ADRs (solicited/unsolicited)	11696					911					11732				
Number of doses with ADRs	121	6590	3833	1058	94	1	675	181	35	19	118	6589	3864	1069	92
Incidence proportion of ADRs (%)	0.8	43.4	25.3	7.0	0.6	0.0	4.4	1.2	0.2	0.1	0.8	43.4	25.5	7.0	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	3 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	8 (0.1)	3 (0.0)	2 (0.0)	1 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (0.1)	3 (0.0)	0 (0.0)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.0)	0 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Hypotension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral coldness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	33 (0.2)	5 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	33 (0.2)	5 (0.0)	1 (0.0)	0 (0.0)
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinorrhoea	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Sneezing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	2 (0.0)	0 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 8-6 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events						Unsolicited adverse events						Combined*									
	Severity						Severity						Severity									
	0	1	2	3	Unknown		0	1	2	3	Unknown		0	1	2	3	Unknown					
Number of doses	15771						15771						15771									
Number of doses with ADRs (solicited/unsolicited)	11696						911						11732									
Number of doses with ADRs	121	6590	3833	1058	94		1	675	181	35	19		118	6589	3864	1069	92					
Incidence proportion of ADRs (%)	0.8	43.4	25.3	7.0	0.6		0.0	4.4	1.2	0.2	0.1		0.8	43.4	25.5	7.0	0.6					
Type of ADR	Number of doses with ADRs (%)						Number of doses with ADRs (%)						Number of doses with ADRs (%)									
Gastrointestinal disorders	0	(0.0)	689	(4.5)	138	(0.9)	27	(0.2)	11	(0.1)			0	(0.0)	722	(4.8)	148	(1.0)	29	(0.2)	12	(0.1)
Abdominal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain	0	(0.0)	254	(1.7)	46	(0.3)	6	(0.0)	8	(0.1)	0	(0.0)	2	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)
Abdominal pain upper	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	3	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	3	(0.0)
Cheilitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Diarrhoea	0	(0.0)	331	(2.2)	49	(0.3)	7	(0.0)	5	(0.0)	7	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	337	(2.2)	49	(0.3)
Gingival pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Melacna	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Nausea	0	(0.0)	330	(2.2)	74	(0.5)	17	(0.1)	8	(0.1)	2	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	332	(2.2)	75	(0.5)
Oral discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Salivary gland pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Stomatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	1	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	1	(0.0)
Tongue rough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Toothache	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	1	(0.0)
Vomiting	0	(0.0)	52	(0.3)	23	(0.2)	8	(0.1)	5	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)	52	(0.3)	24	(0.2)
Lip blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Hypoaesthesia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Paraesthesia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Tongue exfoliation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Oral mucosa erosion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Loose tooth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Facies soft	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Anal incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Oral mucosal roughening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)

Table 8-6 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

Cumulative vaccination	Solicited adverse events					Unsolicited adverse events					Combined*				
	Severity					Severity					Severity				
	0	1	2	3	Unknown	0	1	2	3	Unknown	0	1	2	3	Unknown
Number of doses	15771					15771					15771				
Number of doses with ADRs (solicited/unsolicited)	11696					911					11732				
Number of doses with ADRs	121	6590	3833	1058	94	1	675	181	35	19	118	6589	3864	1069	92
Incidence proportion of ADRs (%)	0.8	43.4	25.3	7.0	0.6	0.0	4.4	1.2	0.2	0.1	0.8	43.4	25.5	7.0	0.6
Type of ADR	Number of doses with ADRs (%)					Number of doses with ADRs (%)					Number of doses with ADRs (%)				
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	152 (1.0)	19 (0.1)	1 (0.0)	5 (0.0)	0 (0.0)	152 (1.0)	19 (0.1)	1 (0.0)	5 (0.0)
Blister	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Erythema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain of skin	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	101 (0.7)	13 (0.1)	1 (0.0)	2 (0.0)	0 (0.0)	101 (0.7)	13 (0.1)	1 (0.0)	2 (0.0)
Purpura	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (0.1)	3 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	16 (0.1)	3 (0.0)	0 (0.0)	2 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (0.1)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	13 (0.1)	2 (0.0)	0 (0.0)	1 (0.0)
Skin tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Skin induration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin burning sensation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	3 (0.0)	3466 (22.8)	758 (5.0)	132 (0.9)	94 (0.6)	0 (0.0)	105 (0.7)	62 (0.4)	15 (0.1)	2 (0.0)	3 (0.0)	3496 (23.0)	789 (5.2)	139 (0.9)	93 (0.6)
Arthralgia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	54 (0.4)	29 (0.2)	9 (0.1)	1 (0.0)	0 (0.0)	54 (0.4)	29 (0.2)	9 (0.1)	1 (0.0)
Back pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	20 (0.1)	18 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)	20 (0.1)	18 (0.1)	1 (0.0)	0 (0.0)
Bone pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Flank pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Groin pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)
Muscular weakness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	1 (0.0)	0 (0.0)
Myalgia	3 (0.0)	3466 (22.8)	758 (5.0)	132 (0.9)	94 (0.6)	0 (0.0)	7 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	3 (0.0)	3472 (22.9)	759 (5.0)	134 (0.9)	94 (0.6)
Neck pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	7 (0.0)	2 (0.0)	1 (0.0)	0 (0.0)
Pain in extremity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	5 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.1)	5 (0.0)	0 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Muscle tightness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.1)	5 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.0)	5 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	6 (0.0)	5 (0.0)	2 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Pollakiuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

Table 8-6 Incidence of ADRs by severity

As of Sep 8, 2025

Subjects included in safety analysis

Cumulative vaccination

	Solicited adverse events						Unsolicited adverse events						Combined*															
	Severity						Severity						Severity															
	0	1	2	3	Unknown		0	1	2	3	Unknown		0	1	2	3	Unknown											
Number of doses	15171						15171						15171															
Number of doses with ADRs (solicited/unsolicited)	11696						911						11732															
Number of doses with ADRs	121	6590	3833	1058	94		1	675	181	35	19		118	6589	3864	1069	92											
Incidence proportion of ADRs (%)	0.8	43.4	25.3	7.0	0.6		0.0	4.4	1.2	0.2	0.1		0.8	43.4	25.5	7.0	0.6											
Type of ADR	Number of doses with ADRs (%)						Number of doses with ADRs (%)						Number of doses with ADRs (%)															
General disorders and administration site conditions	144	(0.9)	6691	(44.1)	3683	(24.3)	999	(6.6)	95	(0.6)	1	(0.0)	349	(2.3)	58	(0.4)	7	(0.0)	142	(0.9)	6699	(44.2)	3699	(24.4)	1003	(6.6)	94	(0.6)
Asthma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	2	(0.0)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)	3	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)	3	(0.0)	0	(0.0)
Chills	0	(0.0)	1198	(7.9)	394	(2.6)	114	(0.8)	26	(0.2)	0	(0.0)	5	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1204	(7.9)	394	(2.6)	115	(0.8)
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Fatigue	2	(0.0)	3204	(21.1)	1029	(6.8)	207	(1.4)	94	(0.6)	0	(0.0)	13	(0.1)	0	(0.0)	1	(0.0)	0	(0.0)	2	(0.0)	3218	(21.2)	1029	(6.8)	208	(1.4)
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.0)	1	(0.0)	0	(0.0)
Injection site paraesthesia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	27	(0.2)	18	(0.1)	3	(0.0)	1	(0.0)	0	(0.0)	27	(0.2)	18	(0.1)	3	(0.0)
Mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.0)	5	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	6	(0.0)	5	(0.0)	0	(0.0)
Pyrexia	1294	(8.5)	2191	(14.4)	904	(6.0)	68	(0.4)	48	(0.3)	3	(0.0)	4	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1297	(8.5)	2195	(14.5)	905	(6.0)	68	(0.4)
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	5	(0.0)	5	(0.0)	1	(0.0)	0	(0.0)
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Axillary pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)	4	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)	4	(0.0)	0	(0.0)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	1	(0.0)	0	(0.0)
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site erythema	1062	(7.0)	2752	(18.1)	1776	(11.7)	518	(3.4)	123	(0.8)	1	(0.0)	8	(0.1)	4	(0.0)	0	(0.0)	0	(0.0)	1063	(7.0)	2761	(18.2)	1780	(11.7)	519	(3.4)
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)
Vaccination site pain	3	(0.0)	8751	(57.7)	1617	(10.7)	219	(1.4)	197	(1.3)	0	(0.0)	15	(0.1)	0	(0.0)	1	(0.0)	0	(0.0)	3	(0.0)	8767	(57.8)	1617	(10.7)	220	(1.5)
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	246	(1.6)	16	(0.1)	0	(0.0)	4	(0.0)	0	(0.0)	246	(1.6)	16	(0.1)	0	(0.0)
Vaccination site discolouration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)
Vaccination site haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Vaccination site swelling	1198	(7.9)	3244	(21.4)	1566	(10.3)	413	(2.7)	139	(0.9)	0	(0.0)	6	(0.0)	5	(0.0)	0	(0.0)	0	(0.0)	1198	(7.9)	3251	(21.4)	1571	(10.4)	413	(2.7)
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	(0.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	(0.1)	1	(0.0)	0	(0.0)
Vaccination site eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)	0	(0.0)	1	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	1	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heat illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)

*If there are multiple events with the same SOC and PT in the same subject, the events will be adopted based on the following priority: Grade 3 > 2 > 1 > 0 > Unknown.

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

MedDRA J (28.0)

Table 9-1 Time to ADR onset (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination (N = 7707)

Type of ADR	Time to ADR onset (days)*1																	
	Solicited adverse events								Unsolicited adverse events					Combined total				
	1	2	3	4	5	6	7	Total number of doses with ADRs (%)#4	≤7	7< to ≤15	15< to ≤30	Unknown #2	Total number of doses with ADRs (%)#4	≤7	7< to ≤15	15< to ≤30	Unknown #2*3	Total number of doses with ADRs (%) #3*4
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type					Number of doses with ADRs by type				
General disorders and administration site conditions	5172	850	43	12	3	2	2	6084 (78.9)	230	13	6	0	249 (3.2)	6087	3	4	1	6095 (79.1)
Vaccination site pain	4832	814	43	12	3	2	3	5709 (74.1)	0	3	3	0	6 (0.1)	5709	3	3	1	5716 (74.2)
Vaccination site swelling	2124	989	127	16	5	2	6	3269 (42.4)	0	0	4	0	4 (0.1)	3269	0	4	1	3274 (42.5)
Vaccination site erythema	1548	1213	303	39	12	10	7	3132 (40.6)	0	0	3	0	3 (0.0)	3132	0	3	1	3136 (40.7)
Fatigue	1121	1128	45	11	7	5	1	2318 (30.1)	0	3	2	0	5 (0.1)	2318	3	2	1	2324 (30.2)
Pyrexia	901	1169	44	8	5	2	3	2132 (27.7)	0	1	2	0	3 (0.0)	2132	1	2	0	2135 (27.7)
Chills	417	353	14	2	3	1	1	791 (10.3)	0	1	2	0	3 (0.0)	791	1	2	1	795 (10.3)
Vaccination site pruritus	0	0	0	0	0	0	0	0 (0.0)	149	5	1	0	155 (2.0)	149	5	1	0	155 (2.0)
Malaise	0	0	0	0	0	0	0	0 (0.0)	28	0	1	0	29 (0.4)	28	0	1	0	29 (0.4)
Vaccination site warmth	0	0	0	0	0	0	0	0 (0.0)	10	0	0	0	10 (0.1)	10	0	0	0	10 (0.1)
Chest pain	0	0	0	0	0	0	0	0 (0.0)	8	1	0	0	9 (0.1)	8	1	0	0	9 (0.1)
Axillary pain	0	0	0	0	0	0	0	0 (0.0)	9	0	0	0	9 (0.1)	9	0	0	0	9 (0.1)
Pain	0	0	0	0	0	0	0	0 (0.0)	6	2	0	0	8 (0.1)	6	2	0	0	8 (0.1)
Swelling	0	0	0	0	0	0	0	0 (0.0)	7	0	0	0	7 (0.1)	7	0	0	0	7 (0.1)
Thirst	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Feeling abnormal	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)
Peripheral swelling	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)
Asthenia	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Feeling hot	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Oedema peripheral	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Vaccination site induration	0	0	0	0	0	0	0	0 (0.0)	2	0	1	0	3 (0.0)	2	0	1	0	3 (0.0)
Condition aggravated	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Swelling face	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Mass	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)
Injected limb mobility decreased	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site reaction	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site discolouration	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)
Vaccination site discomfort	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)
Vaccination site rash	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site bruising	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site eczema	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site mass	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)

Table 9-1 Time to ADR onset (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination (N = 7707)

	Time to ADR onset (days)*1																			
	Solicited adverse events								Unsolicited adverse events						Combined total					
	1	2	3	4	5	6	7	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4		
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type						Number of doses with ADRs by type					
Musculoskeletal and connective tissue disorders	1504	751	52	9	4	4	0	2324 (30.2)	89	9	3	0	101 (1.3)	2349	5	3	0	2357 (30.6)		
Myalgia	1504	751	52	9	4	4	0	2324 (30.2)	0	2	2	0	4 (0.1)	2324	2	2	0	2328 (30.2)		
Arthralgia	0	0	0	0	0	0	0	0 (0.0)	49	2	1	0	52 (0.7)	49	2	1	0	52 (0.7)		
Back pain	0	0	0	0	0	0	0	0 (0.0)	17	2	0	0	19 (0.2)	17	2	0	0	19 (0.2)		
Pain in extremity	0	0	0	0	0	0	0	0 (0.0)	6	3	1	0	10 (0.1)	6	3	1	0	10 (0.1)		
Musculoskeletal stiffness	0	0	0	0	0	0	0	0 (0.0)	8	1	0	0	9 (0.1)	8	1	0	0	9 (0.1)		
Neck pain	0	0	0	0	0	0	0	0 (0.0)	6	1	0	0	7 (0.1)	6	1	0	0	7 (0.1)		
Musculoskeletal pain	0	0	0	0	0	0	0	0 (0.0)	3	0	1	0	4 (0.1)	3	0	1	0	4 (0.1)		
Bone pain	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)		
Muscle spasms	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)		
Muscle tightness	0	0	0	0	0	0	0	0 (0.0)	1	1	0	0	2 (0.0)	1	1	0	0	2 (0.0)		
Groin pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Muscular weakness	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Musculoskeletal chest pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Nervous system disorders	784	847	69	15	6	9	0	1730 (22.4)	61	4	3	0	68 (0.9)	1756	2	3	1	1762 (22.9)		
Headache	784	847	69	15	6	9	0	1730 (22.4)	0	3	3	0	6 (0.1)	1730	2	3	1	1736 (22.5)		
Dizziness	0	0	0	0	0	0	0	0 (0.0)	23	1	0	0	24 (0.3)	23	1	0	0	24 (0.3)		
Somnolence	0	0	0	0	0	0	0	0 (0.0)	15	0	0	0	15 (0.2)	15	0	0	0	15 (0.2)		
Hypoaesthesia	0	0	0	0	0	0	0	0 (0.0)	6	0	0	0	6 (0.1)	6	0	0	0	6 (0.1)		
Paraesthesia	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)		
Neuralgia	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)		
Head discomfort	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)		
Balance disorder	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)		
Taste disorder	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)		
Dizziness postural	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Dysaesthesia	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)		
Dysgeusia	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Movement disorder	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Parosmia	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Tremor	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		
Brain fog	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)		

Table 9-1 Time to ADR onset (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis
Initial vaccination (N = 7707)

Initial vaccination (N = 7/0/1)	Time to ADR onset (days)*1																		
	Solicited adverse events								Unsolicited adverse events					Combined total					
1	2	3	4	5	6	7	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4		
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type					Number of doses with ADRs by type					
Gastrointestinal disorders	185	207	49	23	9	4	1	478 (6.2)	31	8	1	0	40 (0.5)	499	5	1	0	505 (6.6)	
Diarrhoea	68	93	43	16	11	2	1	234 (3.0)	0	3	0	0	3 (0.0)	234	2	0	0	236 (3.1)	
Nausea	106	99	11	4	2	2	0	224 (2.9)	0	1	2	0	3 (0.0)	224	1	2	0	227 (2.9)	
Abdominal pain	59	59	23	11	4	3	1	160 (2.1)	0	2	0	0	2 (0.0)	160	2	0	0	162 (2.1)	
Vomiting	29	15	5	4	0	1	0	54 (0.7)	0	1	0	0	1 (0.0)	54	1	0	0	55 (0.7)	
Abdominal pain upper	0	0	0	0	0	0	0	0 (0.0)	7	0	0	0	7 (0.1)	7	0	0	0	7 (0.1)	
Stomatitis	0	0	0	0	0	0	0	0 (0.0)	6	1	0	0	7 (0.1)	6	1	0	0	7 (0.1)	
Abdominal discomfort	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)	
Gingival swelling	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Salivary gland pain	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Toothache	0	0	0	0	0	0	0	0 (0.0)	1	1	0	0	2 (0.0)	1	1	0	0	2 (0.0)	
Constipation	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Glossitis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Glossodynia	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Lip swelling	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Oral discomfort	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Oral pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Tongue rough	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Hypoaesthesia oral	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)	
Paraesthesia oral	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Tongue exfoliation	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Loose tooth	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Oral mucosal roughening	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Skin and subcutaneous tissue disorders	0	0	0	0	0	0	0	0 (0.0)	109	4	2	0	115 (1.5)	109	4	2	0	115 (1.5)	
Pruritus	0	0	0	0	0	0	0	0 (0.0)	72	1	0	0	73 (0.9)	72	1	0	0	73 (0.9)	
Rash	0	0	0	0	0	0	0	0 (0.0)	19	0	0	0	19 (0.2)	19	0	0	0	19 (0.2)	
Urticaria	0	0	0	0	0	0	0	0 (0.0)	7	3	1	0	11 (0.1)	7	3	1	0	11 (0.1)	
Erythema	0	0	0	0	0	0	0	0 (0.0)	10	0	0	0	10 (0.1)	10	0	0	0	10 (0.1)	
Eczema	0	0	0	0	0	0	0	0 (0.0)	7	0	1	0	8 (0.1)	7	0	1	0	8 (0.1)	
Blister	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Pain of skin	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Rash erythematous	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Night sweats	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Perioral dermatitis	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)	
Purpura	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Scab	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Skin discolouration	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Circumoral swelling	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	

Table 9-1 Time to ADR onset (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis
Initial vaccination (N = 7707)

Initial vaccination (N = 7/07)	Time to ADR onset (days)*1																		
	Solicited adverse events								Unsolicited adverse events					Combined total					
1	2	3	4	5	6	7	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4		
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type					Number of doses with ADRs by type					
Respiratory, thoracic and mediastinal disorders	0	0	0	0	0	0	0	0 (0.0)	27	1	2	0	30 (0.4)	27	1	2	0	30 (0.4)	
Oropharyngeal pain	0	0	0	0	0	0	0	0 (0.0)	8	0	2	0	10 (0.1)	8	0	2	0	10 (0.1)	
Rhinorrhoea	0	0	0	0	0	0	0	0 (0.0)	6	1	0	0	7 (0.1)	6	1	0	0	7 (0.1)	
Cough	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)	
Epistaxis	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)	
Sneezing	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)	
Dyspnoea	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Yawning	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Oropharyngeal discomfort	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Nasal congestion	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Nasal pruritus	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Blood and lymphatic system disorders	0	0	0	0	0	0	0	0 (0.0)	18	0	0	0	18 (0.2)	18	0	0	0	18 (0.2)	
Lymphadenopathy	0	0	0	0	0	0	0	0 (0.0)	13	0	0	0	13 (0.2)	13	0	0	0	13 (0.2)	
Lymph node pain	0	0	0	0	0	0	0	0 (0.0)	6	0	0	0	6 (0.1)	6	0	0	0	6 (0.1)	
Metabolism and nutrition disorders	0	0	0	0	0	0	0	0 (0.0)	14	0	1	0	15 (0.2)	14	0	1	0	15 (0.2)	
Decreased appetite	0	0	0	0	0	0	0	0 (0.0)	14	0	1	0	15 (0.2)	14	0	1	0	15 (0.2)	
Ear and labyrinth disorders	0	0	0	0	0	0	0	0 (0.0)	11	1	0	0	12 (0.2)	11	1	0	0	12 (0.2)	
Tinnitus	0	0	0	0	0	0	0	0 (0.0)	4	1	0	0	5 (0.1)	4	1	0	0	5 (0.1)	
Ear discomfort	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)	
Ear pain	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Ear pruritus	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Hypoacusis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Vascular disorders	0	0	0	0	0	0	0	0 (0.0)	11	1	0	0	12 (0.2)	11	1	0	0	12 (0.2)	
Peripheral coldness	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)	
Hot flush	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)	
Hypotension	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)	
Flushing	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)	
Internal haemorrhage	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Infections and infestations	0	0	0	0	0	0	0	0 (0.0)	5	4	1	0	10 (0.1)	5	4	1	0	10 (0.1)	
Oral herpes	0	0	0	0	0	0	0	0 (0.0)	2	2	0	0	4 (0.1)	2	2	0	0	4 (0.1)	
Conjunctivitis	0	0	0	0	0	0	0	0 (0.0)	0	0	1	0	1 (0.0)	0	0	1	0	1 (0.0)	
Gastroenteritis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Gastroenteritis viral	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Herpes virus infection	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)	
Herpes zoster	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)	
Rhinitis	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)	

Table 9-1 Time to ADR onset (First vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Initial vaccination (N = 7707)

	Time to ADR onset (days)*1																	
	Solicited adverse events								Unsolicited adverse events						Combined total			
	1	2	3	4	5	6	7	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type						Number of doses with ADRs by type			
Eye disorders	0	0	0	0	0	0	0	0 (0.0)	7	0	0	0	7 (0.1)	7	0	0	0	7 (0.1)
Eye pain	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Eye irritation	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vision blurred	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Visual acuity reduced	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Eye pruritus	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Periorbital swelling	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Eyelid irritation	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Investigations	0	0	0	0	0	0	0	0 (0.0)	7	0	0	0	7 (0.1)	7	0	0	0	7 (0.1)
Blood pressure increased	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Heart rate increased	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
C-reactive protein increased	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Heart rate	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Oxygen saturation	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Cardiac disorders	0	0	0	0	0	0	0	0 (0.0)	6	0	0	0	6 (0.1)	6	0	0	0	6 (0.1)
Palpitations	0	0	0	0	0	0	0	0 (0.0)	6	0	0	0	6 (0.1)	6	0	0	0	6 (0.1)
Renal and urinary disorders	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Pollakiuria	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Haematuria	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Nocturia	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Psychiatric disorders	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Euphoric mood	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Injury, poisoning and procedural complications	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Heat illness	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Number of doses with ADRs (%)*5	5249 (85.5)	826 (13.5)	43 (0.7)	12 (0.2)	3 (0.0)	2 (0.0)	2 (0.0)	6137 (79.6)	496 (91.5)	34 (6.3)	12 (2.2)	0 (0.0)	542 (7.0)	6148 (99.8)	5 (0.1)	4 (0.1)	1 (0.0)	6158 (79.9)
Cumulative number of doses with ADRs (%)*6	5249 (85.5)	6075 (99.0)	6118 (99.7)	6130 (99.9)	6133 (99.9)	6135 (100.0)	6137 (100.0)	—	496 (91.5)	530 (97.8)	542 (100.0)	542 (100.0)	—	6148 (99.8)	6153 (99.9)	6157 (100.0)	6158 (100.0)	—

MedDRA/J (28.0)

*1: If ADRs with the same PT occurred multiple times in the same dose, the ADRs were tabulated using the number of treatment days to the onset of the initial ADR.

*2: For doses with unknown date of ADR onset, data were tabulated as doses with unknown time to ADR onset for both initial vaccination and cumulative vaccination.

*3: If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

*4: Data were tabulated by excluding duplicate doses in each treatment category and each type of ADR.

*5: (Number of doses with ADRs/Total number of doses)*100

*6: (Cumulative number of doses with ADRs across days since vaccination/Total number of doses)*100

Table 9-2 Time to ADR onset (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination (N = 7464)

	Time to ADR onset (days)*1																	
	Solicited adverse events								Unsolicited adverse events						Combined total			
	1	2	3	4	5	6	7	Total number of doses with ADRs (%) *4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%) *4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type						Number of doses with ADRs by type			
General disorders and administration site conditions	4755	746	21	4	1	0	1	5528 (74.1)	157	14	2	0	173 (2.3)	5532	8	2	0	5542 (74.2)
Vaccination site pain	4360	673	29	10	3	1	2	5078 (68.0)	0	8	2	0	10 (0.1)	5078	8	2	0	5088 (68.2)
Vaccination site swelling	2350	872	58	9	2	0	0	3291 (44.1)	0	5	2	0	7 (0.1)	3291	5	2	0	3298 (44.2)
Vaccination site erythema	1889	1055	145	7	3	0	0	3099 (41.5)	0	8	2	0	10 (0.1)	3099	8	2	0	3109 (41.7)
Pyrexia	1154	1181	33	4	1	0	0	2373 (31.8)	0	3	2	0	5 (0.1)	2373	3	2	0	2378 (31.9)
Fatigue	1207	967	33	5	2	3	1	2218 (29.7)	0	6	3	0	9 (0.1)	2218	6	3	0	2227 (29.8)
Chills	556	370	13	1	0	1	0	941 (12.6)	0	1	2	0	3 (0.0)	941	1	2	0	944 (12.6)
Vaccination site pruritus	0	0	0	0	0	0	0	0 (0.0)	111	0	0	0	111 (1.5)	111	0	0	0	111 (1.5)
Malaise	0	0	0	0	0	0	0	0 (0.0)	20	0	0	0	20 (0.3)	20	0	0	0	20 (0.3)
Vaccination site warmth	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Chest pain	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)
Pain	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)
Feeling abnormal	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Feeling hot	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Asthenia	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Feeling cold	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Axillary pain	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Vaccination site discolouration	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Discomfort	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Facial pain	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)
Injection site paraesthesia	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)
Thirst	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site haemorrhage	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site bruising	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site vesicles	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vaccination site eczema	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)

Table 9-2 Time to ADR onset (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis
Second vaccination (N = 7464)

Type of ADR	Time to ADR onset (days)*1																	
	Solicited adverse events								Unsolicited adverse events						Combined total			
	1	2	3	4	5	6	7	Total number of doses with ADRs (%) *4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%) *4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type						Number of doses with ADRs by type			
Musculoskeletal and connective tissue disorders	1357	722	41	4	2	1	2	2129 (28.5)	76	6	1	0	83 (1.1)	2157	6	0	0	2163 (29.0)
Myalgia	1357	722	41	4	2	1	2	2129 (28.5)	0	5	1	0	6 (0.1)	2129	5	0	0	2134 (28.6)
Arthralgia	0	0	0	0	0	0	0	0 (0.0)	41	0	0	0	41 (0.5)	41	0	0	0	41 (0.5)
Back pain	0	0	0	0	0	0	0	0 (0.0)	20	0	0	0	20 (0.3)	20	0	0	0	20 (0.3)
Pain in extremity	0	0	0	0	0	0	0	0 (0.0)	5	1	0	0	6 (0.1)	5	1	0	0	6 (0.1)
Musculoskeletal stiffness	0	0	0	0	0	0	0	0 (0.0)	6	0	0	0	6 (0.1)	6	0	0	0	6 (0.1)
Muscle spasms	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)
Neck pain	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Muscular weakness	0	0	0	0	0	0	0	0 (0.0)	1	1	0	0	2 (0.0)	1	1	0	0	2 (0.0)
Flank pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Musculoskeletal pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Rheumatoid arthritis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Muscle tightness	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Musculoskeletal chest pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Nervous system disorders	933	794	51	17	3	5	3	1806 (24.2)	37	4	2	0	43 (0.6)	1823	4	2	0	1829 (24.5)
Headache	933	794	51	17	3	5	3	1806 (24.2)	0	3	2	0	5 (0.1)	1806	3	2	0	1811 (24.3)
Dizziness	0	0	0	0	0	0	0	0 (0.0)	12	1	0	0	13 (0.2)	12	1	0	0	13 (0.2)
Somnolence	0	0	0	0	0	0	0	0 (0.0)	8	0	0	0	8 (0.1)	8	0	0	0	8 (0.1)
Paraesthesia	0	0	0	0	0	0	0	0 (0.0)	5	1	0	0	6 (0.1)	5	1	0	0	6 (0.1)
Hypoaesthesia	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Balance disorder	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Migraine	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Movement disorder	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Neuralgia	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Peroneal nerve palsy	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Brain fog	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)

Table 9-2 Time to ADR onset (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination (N = 7464)

Type of ADR	Time to ADR onset (days)*1																	
	Solicited adverse events								Unsolicited adverse events						Combined total			
	1	2	3	4	5	6	7	Total number of doses with ADRs (%) *4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%) *4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type						Number of doses with ADRs by type			
Gastrointestinal disorders	187	152	23	17	7	0	1	387 (5.2)	22	5	2	0	29 (0.4)	400	4	2	0	406 (5.4)
Nausea	110	78	10	4	2	0	1	205 (2.7)	0	1	0	0	1 (0.0)	205	1	0	0	206 (2.8)
Diarrhoea	61	54	18	17	5	2	1	158 (2.1)	0	4	1	0	5 (0.1)	158	4	1	0	163 (2.2)
Abdominal pain	77	53	13	8	1	1	1	154 (2.1)	0	1	1	0	2 (0.0)	154	1	1	0	156 (2.1)
Vomiting	15	15	1	2	0	0	1	34 (0.5)	0	2	0	0	2 (0.0)	34	2	0	0	36 (0.5)
Abdominal discomfort	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Abdominal pain upper	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Stomatitis	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Toothache	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Cheilitis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Constipation	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Gingival pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Lip swelling	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Melaena	0	0	0	0	0	0	0	0 (0.0)	0	1	0	0	1 (0.0)	0	1	0	0	1 (0.0)
Oral pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Lip blister	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Paraesthesia oral	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Oral mucosa erosion	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Faeces soft	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Anal incontinence	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Skin and subcutaneous tissue disorders	0	0	0	0	0	0	0	0 (0.0)	61	1	0	0	62 (0.8)	61	1	0	0	62 (0.8)
Pruritus	0	0	0	0	0	0	0	0 (0.0)	43	1	0	0	44 (0.6)	43	1	0	0	44 (0.6)
Urticaria	0	0	0	0	0	0	0	0 (0.0)	5	0	0	0	5 (0.1)	5	0	0	0	5 (0.1)
Eczema	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Erythema	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Rash	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Skin tightness	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Skin burning sensation	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Dermatitis contact	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Night sweats	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Perioral dermatitis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Rash pruritic	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Skin induration	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Butterfly rash	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Metabolism and nutrition disorders	0	0	0	0	0	0	0	0 (0.0)	12	0	0	0	12 (0.2)	12	0	0	0	12 (0.2)
Decreased appetite	0	0	0	0	0	0	0	0 (0.0)	12	0	0	0	12 (0.2)	12	0	0	0	12 (0.2)

Table 9-2 Time to ADR onset (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis

Second vaccination (N = 7464)

Type of ADR	Time to ADR onset (days)*1																	
	Solicited adverse events								Unsolicited adverse events						Combined total			
	1	2	3	4	5	6	7	Total number of doses with ADRs (%)#4	≤7	7< to ≤15	15< to ≤30	Unknown #2	Total number of doses with ADRs (%)#4	≤7	7< to ≤15	15< to ≤30	Unknown #2#3	Total number of doses with ADRs (%) #3#4
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type						Number of doses with ADRs by type			
Respiratory, thoracic and mediastinal disorders	0	0	0	0	0	0	0	0 (0.0)	8	0	1	0	9 (0.1)	8	0	1	0	9 (0.1)
Rhinorrhoea	0	0	0	0	0	0	0	0 (0.0)	2	0	1	0	3 (0.0)	2	0	1	0	3 (0.0)
Oropharyngeal pain	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Dyspnoea	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Productive cough	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Cough	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Upper respiratory tract inflammation	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Oropharyngeal discomfort	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Renal and urinary disorders	0	0	0	0	0	0	0	0 (0.0)	8	0	0	0	8 (0.1)	8	0	0	0	8 (0.1)
Pollakiuria	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Nocturia	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Polyuria	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Urethral pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Urinary incontinence	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Blood and lymphatic system disorders	0	0	0	0	0	0	0	0 (0.0)	7	0	0	0	7 (0.1)	7	0	0	0	7 (0.1)
Lymphadenopathy	0	0	0	0	0	0	0	0 (0.0)	6	0	0	0	6 (0.1)	6	0	0	0	6 (0.1)
Lymph node pain	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Eye disorders	0	0	0	0	0	0	0	0 (0.0)	5	0	2	0	7 (0.1)	5	0	2	0	7 (0.1)
Eye discharge	0	0	0	0	0	0	0	0 (0.0)	1	0	1	0	2 (0.0)	1	0	1	0	2 (0.0)
Eye pain	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Eye inflammation	0	0	0	0	0	0	0	0 (0.0)	0	0	1	0	1 (0.0)	0	0	1	0	1 (0.0)
Retinal haemorrhage	0	0	0	0	0	0	0	0 (0.0)	0	0	1	0	1 (0.0)	0	0	1	0	1 (0.0)
Swelling of eyelid	0	0	0	0	0	0	0	0 (0.0)	0	0	1	0	1 (0.0)	0	0	1	0	1 (0.0)
Eye pruritus	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Periorbital swelling	0	0	0	0	0	0	0	0 (0.0)	0	0	1	0	1 (0.0)	0	0	1	0	1 (0.0)
Eyelid pain	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Cardiac disorders	0	0	0	0	0	0	0	0 (0.0)	7	0	0	0	7 (0.1)	7	0	0	0	7 (0.1)
Palpitations	0	0	0	0	0	0	0	0 (0.0)	7	0	0	0	7 (0.1)	7	0	0	0	7 (0.1)
Ear and labyrinth disorders	0	0	0	0	0	0	0	0 (0.0)	5	1	0	0	6 (0.1)	5	1	0	0	6 (0.1)
Ear pain	0	0	0	0	0	0	0	0 (0.0)	2	1	0	0	3 (0.0)	2	1	0	0	3 (0.0)
Tinnitus	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Hypacusis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Psychiatric disorders	0	0	0	0	0	0	0	0 (0.0)	4	0	0	0	4 (0.1)	4	0	0	0	4 (0.1)
Dissociative disorder	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Euphoric mood	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Hallucination	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Listless	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)

Table 9-2 Time to ADR onset (Second vaccination)

As of Sep 8, 2025

Subjects included in safety analysis
Second vaccination (N = 7464)

Type of ADR	Time to ADR onset (days)*1																	
	Solicited adverse events								Unsolicited adverse events						Combined total			
	1	2	3	4	5	6	7	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2	Total number of doses with ADRs (%)*4	≤7	7< to ≤15	15< to ≤30	Unknown *2*3	Total number of doses with ADRs (%) *3*4
Type of ADR	Number of doses with ADRs by type								Number of doses with ADRs by type						Number of doses with ADRs by type			
Infections and infestations	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Pustule	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Rhinitis	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Cystitis bacterial	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Vascular disorders	0	0	0	0	0	0	0	0 (0.0)	3	0	0	0	3 (0.0)	3	0	0	0	3 (0.0)
Peripheral coldness	0	0	0	0	0	0	0	0 (0.0)	2	0	0	0	2 (0.0)	2	0	0	0	2 (0.0)
Hypertension	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Investigations	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Heart rate increased	0	0	0	0	0	0	0	0 (0.0)	1	0	0	0	1 (0.0)	1	0	0	0	1 (0.0)
Number of doses with ADRs (%)*5	4811 (86.5)	721 (13.0)	20 (0.4)	5 (0.1)	1 (0.0)	0 (0.0)	1 (0.0)	5559 (74.5)	342 (92.7)	20 (5.4)	7 (1.9)	0 (0.0)	369 (4.9)	5564 (99.8)	8 (0.1)	2 (0.0)	0 (0.0)	5574 (74.7)
Cumulative number of doses with ADRs (%)*6	4811 (86.5)	5532 (99.5)	5552 (99.9)	5557 (100.0)	5558 (100.0)	5558 (100.0)	5559 (100.0)	—	342 (92.7)	362 (98.1)	369 (100.0)	369 (100.0)	—	5564 (99.8)	5572 (100.0)	5574 (100.0)	5574 (100.0)	—

*1: If ADRs with the same PT occurred multiple times in the same dose, the ADRs were tabulated using the number of treatment days to the onset of the initial ADR.

*2: For doses with unknown date of ADR onset, data were tabulated as doses with unknown time to ADR onset for both initial vaccination and cumulative vaccination.

*3: If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

*4: Data were tabulated by excluding duplicate doses in each treatment category and each type of ADR.

*5: (Number of doses with ADRs/Total number of doses)*100

*6: (Cumulative number of doses with ADRs/Total number of doses)*100

MedDRA/J (28.0)

*1: If ADRs with the same PT occurred multiple times in the same dose, the ADRs were tabulated using the number of treatment days to the onset of the initial ADR.

Table 10-1 Univariate logistic regression analysis

As of Sep 8, 2025

Subjects included in safety analysis

Item/Category			Sample size	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Unadjusted odds ratio		
						Point estimate	95% confidence interval	
Total			7707	6406	83.1			
Sex	Male	*	2495	1988	79.7	—	—	—
	Female		5212	4418	84.8	1.419	1.254	1.605
Age 1 [years]	<15		0	0	—	—	—	—
	15≤ to <50		91	78	85.7	1.049	0.579	1.902
	50≤ to <65	*	3406	2899	85.1	—	—	—
	65≤ to <75		2524	2128	84.3	0.940	0.815	1.084
	75≤		1686	1301	77.2	0.591	0.510	0.685
Age 2 [years]	<65	*	3497	2977	85.1	—	—	—
	65≤		4210	3429	81.4	0.767	0.679	0.866
History of vaccination with herpes zoster vaccine other than Shingrix	No	*	7285	6042	82.9	—	—	—
	Yes		115	96	83.5	1.039	0.633	1.706
History of herpes zoster	No	*	6221	5125	82.4	—	—	—
	Yes		742	636	85.7	1.283	1.034	1.592
Eligibility as subjects requiring precaution for vaccination	No	*	7668	6370	83.1	—	—	—
	Yes		39	36	92.3	2.445	0.752	7.950
Immune abnormality	No	*	7005	5770	82.4	—	—	—
	Yes		702	636	90.6	2.063	1.589	2.677
Underlying diseases related to immune abnormalities	No	*	7035	5798	82.4	—	—	—
	Yes		672	608	90.5	2.027	1.555	2.641
Prior medications (drugs that may affect immunity)	No	*	7072	5832	82.5	—	—	—
	Yes		635	574	90.4	2.001	1.526	2.623
Prior therapies (therapies that may affect immunity)	No	*	7699	6400	83.1	—	—	—
	Yes		8	6	75.0	—	—	—
Underlying disease [†]	No	*	3761	2938	78.1	—	—	—
	Yes		3946	3468	87.9	2.032	1.797	2.298
Underlying disease (kidney disease)	No	*	7597	6315	83.1	—	—	—
	Yes		110	91	82.7	0.972	0.591	1.599
Underlying disease (liver disease)	No	*	7541	6264	83.1	—	—	—
	Yes		166	142	85.5	1.206	0.779	1.867
Underlying disease (other)	No	*	3795	2966	78.2	—	—	—
	Yes		3912	3440	87.9	2.037	1.801	2.304
Medical history	No	*	7073	5839	82.6	—	—	—
	Yes		634	567	89.4	1.788	1.378	2.321

[†] “Underlying diseases” include underlying diseases related to immune abnormality, kidney diseases, liver diseases, and others

Table 10-2 Correlation between individual factors

As of Sep 8, 2025

Subjects included in safety analysis

Confirmation of correlations among exploratory variables by round-robin cross-tabulation

List of correlation coefficients by item	Sex	Age 1 [years]	Age 2 [years]	History of vaccination with herpes zoster vaccine other than Shingrix	History of herpes zoster	Eligibility as subjects requiring precaution for vaccination	Immune abnormality	Underlying diseases related to immune abnormalities	Prior medications (drugs that may affect immunity)	Prior therapies (therapies that may affect immunity)	Underlying disease*	Underlying disease (kidney disease)	Underlying disease (liver disease)	Underlying disease (other)	Medical history
Sex		0.012	0.012	-0.002	0.030	-0.001	0.086	0.087	0.088	-0.004	0.017	-0.031	0.015	0.018	0.009
Age 1 [years]	0.012		0.926	0.024	0.102	0.014	0.054	0.053	0.054	-0.001	0.218	0.065	0.026	0.216	0.056
Age 2 [years]	0.012	0.926		0.020	0.092	0.017	0.060	0.058	0.060	-0.003	0.211	0.053	0.036	0.211	0.061
History of vaccination with herpes zoster vaccine other than Shingrix	-0.002	0.024	0.020		0.056	0.024	-0.015	-0.013	-0.011	-0.004	0.022	0.013	-0.010	0.018	-0.016
History of herpes zoster	0.030	0.102	0.092	0.056		0.044	0.161	0.163	0.146	0.004	0.126	0.036	0.048	0.126	0.109
Eligibility as subjects requiring precaution for vaccination	-0.001	0.014	0.017	0.024	0.044		0.079	0.082	0.085	0.054	0.066	0.022	0.040	0.063	0.019
Immune abnormality	0.086	0.054	0.060	-0.015	0.161	0.079		0.976	0.947	0.102	0.309	0.118	0.177	0.303	0.150
Underlying diseases related to immune abnormalities	0.087	0.053	0.058	-0.013	0.163	0.082	0.976		0.919	0.104	0.302	0.118	0.173	0.296	0.145
Prior medications (drugs that may affect immunity)	0.088	0.054	0.060	-0.011	0.146	0.085	0.947	0.919		0.049	0.293	0.095	0.180	0.287	0.146
Prior therapies (therapies that may affect immunity)	-0.004	-0.001	-0.003	-0.004	0.004	0.054	0.102	0.104	0.049		0.031	0.166	-0.005	0.016	0.020
Underlying disease*	0.017	0.218	0.211	0.022	0.126	0.066	0.309	0.302	0.293	0.031		0.117	0.145	0.991	0.171
Underlying disease (kidney disease)	-0.031	0.065	0.053	0.013	0.036	0.022	0.118	0.118	0.095	0.166	0.117		0.065	0.066	0.071
Underlying disease (liver disease)	0.015	0.026	0.036	-0.010	0.048	0.040	0.177	0.173	0.180	-0.005	0.145	0.065		0.128	0.148
Underlying disease (other)	0.018	0.216	0.211	0.018	0.126	0.063	0.303	0.296	0.287	0.016	0.991	0.066	0.128		0.169
Medical history	0.009	0.056	0.061	-0.016	0.109	0.019	0.150	0.145	0.146	0.020	0.171	0.071	0.148	0.169	

* "Underlying diseases" include underlying diseases related to immune abnormality, kidney diseases, liver diseases, and others

Table 10-3 Multivariate analysis

As of Sep 8, 2025

Subjects included in safety analysis

Item/Category			Sample size	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Adjusted odds ratio		
						Point estimate	95% confidence interval	
Total	Criteria		6913	5720	82.7			
Sex	Male	*	2255	1790	79.4	—	—	—
	Female		4658	3930	84.4	1.411	1.237	1.610
Age 1 [years]	<15		0	0	—	—	—	—
	15≤ to <50		79	69	87.3	1.215	0.616	2.397
	50≤ to <65	*	3096	2628	84.9	—	—	—
	65≤ to <75		2243	1882	83.9	0.793	0.680	0.924
	75≤		1495	1141	76.3	0.448	0.381	0.527
History of vaccination with herpes zoster vaccine other than Shingrix	No	*	6816	5640	82.7	—	—	—
	Yes		97	80	82.5	0.957	0.559	1.637
History of herpes zoster	No	*	6196	5104	82.4	—	—	—
	Yes		717	616	85.9	1.146	0.912	1.440
Immune abnormality	No	*	6348	5207	82.0	—	—	—
	Yes		565	513	90.8	1.331	0.976	1.814
Underlying disease [†]	No	*	3490	2722	78.0	—	—	—
	Yes		3423	2998	87.6	2.099	1.821	2.419
Medical history	No	*	6380	5239	82.1	—	—	—
	Yes		533	481	90.2	1.652	1.223	2.232

[†] “Underlying diseases” include underlying diseases related to immune abnormality, kidney diseases, liver diseases, and others

Table 11-1 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Age 1 [years]											
	<15			15≤ to <30			30≤ to <65			65≤ to <75		
	Total	Serious		Total	Serious		Total	Serious		Total	Serious	
Sample size	0	0		91			3406			2524	1686	
Number of subjects with ADRs	0	0		78	0		2899	3		2128	0	
Incidence proportion of ADRs (%)	—	—		85.7	0.0		85.1	0.1		84.3	0.1	
Type of ADR	Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)		
General disorders and administration site conditions	0	—	0	76	(83.5)	0	2882	(84.6)	0	2116	(83.8)	0
Vaccination site pain	0	—	0	75	(82.4)	0	2767	(81.2)	0	2030	(80.4)	0
Vaccination site swelling	0	—	0	52	(57.1)	0	1873	(55.0)	0	1419	(56.2)	0
Vaccination site erythema	0	—	0	50	(54.9)	0	1794	(52.7)	0	1367	(54.2)	0
Fatigue	0	—	0	53	(58.2)	0	1670	(49.0)	0	989	(39.2)	0
Pyrexia	0	—	0	52	(57.1)	0	1694	(49.7)	0	958	(38.0)	0
Chills	0	—	0	27	(29.7)	0	882	(25.9)	0	375	(14.9)	0
Vaccination site pruritus	0	—	0	2	(2.2)	0	126	(3.7)	0	60	(2.4)	0
Malaise	0	—	0	0	(0.0)	0	22	(0.6)	0	12	(0.5)	0
Chest pain	0	—	0	0	(0.0)	0	5	(0.1)	0	5	(0.2)	0
Pain	0	—	0	1	(1.1)	0	8	(0.2)	0	1	(0.0)	0
Vaccination site warmth	0	—	0	0	(0.0)	0	6	(0.2)	0	5	(0.2)	0
Axillary pain	0	—	0	0	(0.0)	0	11	(0.3)	0	0	(0.0)	0
Feeling abnormal	0	—	0	0	(0.0)	0	5	(0.1)	0	2	(0.1)	0
Swelling	0	—	0	0	(0.0)	0	5	(0.1)	0	1	(0.0)	0
Thirst	0	—	0	0	(0.0)	0	4	(0.1)	0	2	(0.1)	0
Asthenia	0	—	0	0	(0.0)	0	5	(0.1)	0	0	(0.0)	0
Feeling hot	0	—	0	0	(0.0)	0	3	(0.1)	0	1	(0.0)	0
Peripheral swelling	0	—	0	0	(0.0)	0	3	(0.1)	0	1	(0.0)	0
Oedema peripheral	0	—	0	0	(0.0)	0	1	(0.0)	0	2	(0.1)	0
Vaccination site induration	0	—	0	0	(0.0)	0	1	(0.0)	0	1	(0.0)	0
Vaccination site discolouration	0	—	0	0	(0.0)	0	3	(0.1)	0	0	(0.0)	0
Condition aggravated	0	—	0	0	(0.0)	0	0	(0.0)	0	0	(0.0)	0
Feeling cold	0	—	0	0	(0.0)	0	1	(0.0)	0	1	(0.0)	0
Swelling face	0	—	0	0	(0.0)	0	0	(0.0)	0	2	(0.1)	0
Vaccination site bruising	0	—	0	0	(0.0)	0	1	(0.0)	0	1	(0.0)	0
Vaccination site eczema	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Discomfort	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Facial pain	0	—	0	0	(0.0)	0	0	(0.0)	0	1	(0.0)	0
Injection site paraesthesia	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Mass	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Injected limb mobility decreased	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Vaccination site reaction	0	—	0	0	(0.0)	0	0	(0.0)	0	0	(0.0)	0
Vaccination site haemorrhage	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Vaccination site discomfort	0	—	0	0	(0.0)	0	0	(0.0)	0	1	(0.0)	0
Vaccination site rash	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Vaccination site vesicles	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Vaccination site mass	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Musculoskeletal and connective tissue disorders	0	—	0	54	(59.3)	0	1602	(47.0)	0	993	(39.3)	1
Myalgia	0	—	0	54	(59.3)	0	1582	(46.4)	0	980	(38.8)	0
Arthralgia	0	—	0	2	(2.2)	0	57	(1.7)	0	20	(0.8)	0
Back pain	0	—	0	0	(0.0)	0	24	(0.7)	0	7	(0.3)	0
Pain in extremity	0	—	0	0	(0.0)	0	9	(0.3)	0	3	(0.1)	0
Musculoskeletal stiffness	0	—	0	2	(2.2)	0	7	(0.2)	0	6	(0.2)	0
Neck pain	0	—	0	0	(0.0)	0	7	(0.2)	0	3	(0.1)	0
Muscle spasms	0	—	0	0	(0.0)	0	4	(0.1)	0	1	(0.0)	0
Musculoskeletal pain	0	—	0	0	(0.0)	0	4	(0.1)	0	1	(0.0)	0
Muscular weakness	0	—	0	0	(0.0)	0	2	(0.1)	0	0	(0.0)	0
Muscle tightness	0	—	0	0	(0.0)	0	1	(0.0)	0	2	(0.1)	0
Bone pain	0	—	0	0	(0.0)	0	1	(0.0)	0	1	(0.0)	0
Musculoskeletal chest pain	0	—	0	0	(0.0)	0	0	(0.0)	0	2	(0.1)	0
Flank pain	0	—	0	0	(0.0)	0	1	(0.0)	0	0	(0.0)	0
Groin pain	0	—	0	0	(0.0)	0	0	(0.0)	0	1	(0.0)	0
Rheumatoid arthritis	0	—	0	0	(0.0)	0	0	(0.0)	0	1	(0.0)	1

Table 11-1 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Age 1 [years]															
	<15				15≤ to <30				30≤ to <65				65≤ to <75			
	Total	Serious			Total	Serious			Total	Serious			Total	Serious		
Sample size	0	0			78	91			2899	3406			2128	2524		
Number of subjects with ADRs	0	0			78	0			2899	3			2128	2		
Incidence proportion of ADRs (%)	—	—			83.7	0.0			83.1	0.1			84.3	0.1		
Type of ADR	Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)			
Nervous system disorders	0	—	0	—	48	(52.7)	0	(0.0)	1448	(42.5)	0	(0.0)	763	(30.2)	0	(0.0)
Headache	0	—	0	—	48	(52.7)	0	(0.0)	1440	(42.3)	0	(0.0)	753	(29.8)	0	(0.0)
Dizziness	0	—	0	—	1	(1.1)	0	(0.0)	23	(0.7)	0	(0.0)	8	(0.3)	0	(0.0)
Somnolence	0	—	0	—	0	(0.0)	0	(0.0)	11	(0.3)	0	(0.0)	7	(0.3)	0	(0.0)
Hypoaesthesia	0	—	0	—	1	(1.1)	0	(0.0)	6	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Parosmia	0	—	0	—	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	3	(0.1)	0	(0.0)
Balance disorder	0	—	0	—	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	3	(0.1)	0	(0.0)
Neuralgia	0	—	0	—	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Head discomfort	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Taste disorder	0	—	0	—	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Brain fog	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Dizziness postural	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysaesthesia	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Migraine	0	—	0	—	1	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Movement disorder	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Parosmia	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Peroneal nerve palsy	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tremor	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Gastrointestinal disorders	0	—	0	—	12	(13.2)	0	(0.0)	436	(12.8)	1	(0.0)	208	(8.2)	0	(0.0)
Nausea	0	—	0	—	5	(5.5)	0	(0.0)	225	(6.6)	0	(0.0)	100	(4.0)	0	(0.0)
Diarrhoea	0	—	0	—	5	(5.5)	0	(0.0)	194	(5.7)	0	(0.0)	100	(4.0)	0	(0.0)
Abdominal pain	0	—	0	—	3	(3.3)	0	(0.0)	157	(4.6)	0	(0.0)	79	(3.1)	0	(0.0)
Vomiting	0	—	0	—	1	(1.1)	0	(0.0)	45	(1.3)	0	(0.0)	25	(1.0)	0	(0.0)
Abdominal pain upper	0	—	0	—	0	(0.0)	0	(0.0)	9	(0.3)	0	(0.0)	2	(0.1)	0	(0.0)
Abdominal discomfort	0	—	0	—	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	3	(0.1)	0	(0.0)
Stomatitis	0	—	0	—	0	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Toothache	0	—	0	—	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Gingival swelling	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Oral pain	0	—	0	—	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Salivary gland pain	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Cheilitis	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gingival pain	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glossitis	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Glossodynia	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lip swelling	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Melena	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Oral discomfort	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue rough	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Lip blister	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Hypoaesthesia oral	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Parosmia oral	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue exfoliation	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosa erosion	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Loose tooth	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Faeces soft	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Anal incontinence	0	—	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosal roughening	0	—	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

Table 11-1 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Age 1 [years]														
	<15		15≤ to <30		30≤ to <65		65≤ to <75		75≤		Total				
	Total	Serious	Total	Serious	Total	Serious	Total	Serious	Total	Serious	Total	Serious			
Sample size	0	0	78	91	2899	3406	2128	2524	1301	1686	6406	7707			
Number of subjects with ADRs	0	0	78	0	2899	3	2128	2	1301	0	6406	5			
Incidence proportion of ADRs (%)	—	—	85.7	0.0	85.1	0.1	84.3	0.1	77.2	0.0	83.1	0.1			
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)				
Skin and subcutaneous tissue disorders	0	—	6	(6.6)	0	(0.0)	50	(2.0)	22	(1.3)	106	(2.1)			
Pruritus	0	—	3	(3.3)	0	(0.0)	32	(1.3)	0	(0.0)	162	(1.4)			
Rash	0	—	2	(2.2)	0	(0.0)	10	(0.4)	0	(0.0)	21	(0.3)			
Urticaria	0	—	1	(1.1)	0	(0.0)	4	(0.2)	0	(0.0)	15	(0.2)			
Erythema	0	—	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)	11	(0.1)			
Eczema	0	—	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	9	(0.0)			
Blister	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	2	(0.0)			
Night sweats	0	—	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.0)			
Pain of skin	0	—	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	2	(0.0)			
Perioral dermatitis	0	—	1	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)			
Rash erythematous	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	2	(0.0)			
Skin tightness	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)			
Skin burning sensation	0	—	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)			
Dermatitis contact	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)			
Purpura	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)			
Rash pruritic	0	—	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)			
Scab	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)			
Skin discoloration	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)			
Skin induration	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)			
Butterfly rash	0	—	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)			
Circumoral swelling	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)			
Respiratory, thoracic and mediastinal disorders	0	—	0	(0.0)	25	(0.7)	9	(0.4)	5	(0.3)	39	(0.5)			
Oropharyngeal pain	0	—	0	(0.0)	6	(0.2)	3	(0.1)	4	(0.2)	13	(0.2)			
Rhinorrhoea	0	—	0	(0.0)	8	(0.2)	2	(0.1)	0	(0.0)	10	(0.1)			
Cough	0	—	4	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	5	(0.1)			
Dyspnoea	0	—	0	(0.0)	2	(0.1)	2	(0.1)	0	(0.0)	4	(0.1)			
Epistaxis	0	—	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	3	(0.0)			
Sneezing	0	—	0	(0.0)	2	(0.1)	1	(0.0)	0	(0.0)	3	(0.0)			
Oropharyngeal discomfort	0	—	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	3	(0.0)			
Productive cough	0	—	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)			
Yawning	0	—	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.1)	2	(0.0)			
Nasal congestion	0	—	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)			
Upper respiratory tract inflammation	0	—	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)			
Nasal pruritus	0	—	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)			
Metabolism and nutrition disorders	0	—	0	(0.0)	10	(0.3)	10	(0.4)	6	(0.4)	26	(0.3)			
Decreased appetite	0	—	0	(0.0)	10	(0.3)	10	(0.4)	6	(0.4)	26	(0.3)			
Blood and lymphatic system disorders	0	—	0	(0.0)	17	(0.5)	4	(0.2)	0	(0.0)	21	(0.3)			
Lymphadenopathy	0	—	0	(0.0)	13	(0.4)	3	(0.1)	0	(0.0)	16	(0.2)			
Lymph node pain	0	—	0	(0.0)	5	(0.1)	2	(0.1)	0	(0.0)	7	(0.1)			
Ear and labyrinth disorders	0	—	0	(0.0)	12	(0.4)	1	(0.0)	2	(0.1)	15	(0.2)			
Tinnitus	0	—	0	(0.0)	5	(0.1)	0	(0.0)	1	(0.1)	6	(0.1)			
Ear pain	0	—	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	4	(0.1)			
Ear discomfort	0	—	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	3	(0.0)			
Hypacusis	0	—	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.1)	2	(0.0)			
Ear pruritus	0	—	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)			

Table 11-1 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Age 1 [years]																	
	<15			15≤ to <50			50≤ to <65			65≤ to <75			75≤			Total		
	Total	Serious		Total	Serious		Total	Serious		Total	Serious		Total	Serious		Total	Serious	
Sample size	0	0		78	91		2899	3406		2128	2524		1301	1686		6406	7707	
Number of subjects with ADRs	0	0		78	91		2899	3406		2128	2524		1301	1686		6406	7707	
Incidence proportion of ADRs (%)	0	0		85.7	0.0		85.1	0.1		84.3	0.1		77.2	0.0		83.1	0.1	
Type of ADR	Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)		
Eye disorders	0	0	0	0	0	0	11	0	3	1	0	0	0	0	0	14	0	
Eye pain	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	4	0	
Eye discharge	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	2	0	
Eye pruritus	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	2	0	
Periorbital swelling	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	2	0	
Eye inflammation	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Eye irritation	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Retinal haemorrhage	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	1	0	
Swelling of eyelid	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Vision blurred	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Visual acuity reduced	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Eyelid irritation	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Eyelid pain	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Vascular disorders	0	0	0	0	0	0	11	0	1	1	0	0	2	0	0	14	0	
Peripheral coldness	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0	5	0	
Hot flush	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	4	0	
Hypotension	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	2	0	
Flushing	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	
Hypertension	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	
Internal haemorrhage	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1	0	
Infections and infestations	0	0	0	0	0	0	10	0	0	3	0	0	0	0	0	13	0	
Oral herpes	0	0	0	0	0	0	2	0	0	2	0	0	0	0	0	4	0	
Rhinitis	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	2	0	
Conjunctivitis	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Gastroenteritis	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Gastroenteritis viral	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Herpes virus infection	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Herpes zoster	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Pustule	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Cystitis bacterial	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	
Cardiac disorders	0	0	0	0	0	0	6	0	0	5	0	0	1	0	0	12	0	
Palpitations	0	0	0	0	0	0	6	0	0	5	0	0	1	0	0	12	0	
Renal and urinary disorders	0	0	0	0	0	0	3	0	0	6	0	0	1	0	0	10	0	
Pollakiuria	0	0	0	0	0	0	0	0	0	3	0	0	1	0	0	4	0	
Nocturia	0	0	0	0	0	0	1	0	0	2	0	0	0	0	0	3	0	
Haematuria	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	
Polyuria	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	
Urethral pain	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Urinary incontinence	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Investigations	0	0	0	0	0	0	3	0	0	2	0	0	2	0	0	7	0	
Blood pressure increased	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	3	0	
Heart rate increased	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	2	0	
C-reactive protein increased	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Heart rate	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	
Oxygen saturation	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	
Psychiatric disorders	0	0	0	0	0	0	3	0	1	0	0	0	1	0	0	4	0	
Dissociative disorder	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Euphoric mood	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Hallucination	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	
Lethargy	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	
Injury, poisoning and procedural complications	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	
Heat illness	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	

MedDRA J (28.0)

Table 11-2 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Underlying disease											
	No				Yes							
	Total		Serious		Total		Serious					
Sample size	3761				3946				7707			
Number of subjects with ADRs	2938				3468				6406			
incidence proportion of ADRs (%)	78.1				87.9				83.1			
Type of ADR	Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)			
General disorders and administration site conditions	2916	(77.5)	0	(0.0)	3449	(87.4)	0	(0.0)	6365	(82.6)	0	(0.0)
Vaccination site pain	2784	(74.0)	0	(0.0)	3286	(83.3)	0	(0.0)	6070	(78.8)	0	(0.0)
Vaccination site swelling	1873	(49.8)	0	(0.0)	2318	(58.7)	0	(0.0)	4191	(54.4)	0	(0.0)
Vaccination site erythema	1806	(48.0)	0	(0.0)	2264	(57.4)	0	(0.0)	4070	(52.8)	0	(0.0)
Fatigue	1464	(38.9)	0	(0.0)	1690	(42.8)	0	(0.0)	3154	(40.9)	0	(0.0)
Pyrexia	1467	(39.0)	0	(0.0)	1634	(41.4)	0	(0.0)	3101	(40.2)	0	(0.0)
Chills	668	(17.8)	0	(0.0)	732	(18.6)	0	(0.0)	1400	(18.2)	0	(0.0)
Vaccination site pruritus	59	(1.6)	0	(0.0)	163	(4.1)	0	(0.0)	222	(2.9)	0	(0.0)
Malaise	13	(0.3)	0	(0.0)	31	(0.8)	0	(0.0)	44	(0.6)	0	(0.0)
Chest pain	5	(0.1)	0	(0.0)	8	(0.2)	0	(0.0)	13	(0.2)	0	(0.0)
Pain	5	(0.1)	0	(0.0)	7	(0.2)	0	(0.0)	12	(0.2)	0	(0.0)
Vaccination site warmth	4	(0.1)	0	(0.0)	8	(0.2)	0	(0.0)	12	(0.2)	0	(0.0)
Axillary pain	6	(0.2)	0	(0.0)	5	(0.1)	0	(0.0)	11	(0.1)	0	(0.0)
Feeling abnormal	4	(0.1)	0	(0.0)	3	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)
Swelling	3	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)
Thirst	1	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	6	(0.1)	0	(0.0)
Asthenia	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)
Feeling hot	1	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)
Oedema peripheral	1	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	3	(0.0)	0	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	3	(0.0)	0	(0.0)
Vaccination site discolouration	1	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	3	(0.0)	0	(0.0)
Condition aggravated	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Feeling cold	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Swelling face	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Vaccination site eczema	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Discomfort	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Injection site paraesthesia	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Mass	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Injected limb mobility decreased	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site reaction	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site haemorrhage	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site rash	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site vesicles	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)

Table 11-2 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Underlying disease											
	No		Yes		Total							
	Total	Serious	Total	Serious	Total	Serious						
Sample size	3761		3946		7707							
Number of subjects with ADRs	2938		3468		6406							
incidence proportion of ADRs (%)	78.1		87.9		83.1							
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)							
Musculoskeletal and connective tissue disorders	1453	(38.6)	0	(0.0)	1708	(43.3)	1	(0.0)	3161	(41.0)	1	(0.0)
Myalgia	1446	(38.4)	0	(0.0)	1679	(42.5)	0	(0.0)	3125	(40.5)	0	(0.0)
Arthralgia	26	(0.7)	0	(0.0)	60	(1.5)	0	(0.0)	86	(1.1)	0	(0.0)
Back pain	13	(0.3)	0	(0.0)	21	(0.5)	0	(0.0)	34	(0.4)	0	(0.0)
Pain in extremity	2	(0.1)	0	(0.0)	13	(0.3)	0	(0.0)	15	(0.2)	0	(0.0)
Musculoskeletal stiffness	4	(0.1)	0	(0.0)	11	(0.3)	0	(0.0)	15	(0.2)	0	(0.0)
Neck pain	2	(0.1)	0	(0.0)	8	(0.2)	0	(0.0)	10	(0.1)	0	(0.0)
Muscle spasms	1	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	6	(0.1)	0	(0.0)
Musculoskeletal pain	2	(0.1)	0	(0.0)	3	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)
Muscular weakness	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	3	(0.0)	0	(0.0)
Muscle tightness	1	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	3	(0.0)	0	(0.0)
Bone pain	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Musculoskeletal chest pain	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Flank pain	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Groin pain	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)
Nervous system disorders	1193	(31.7)	0	(0.0)	1371	(34.7)	0	(0.0)	2564	(33.3)	0	(0.0)
Headache	1189	(31.6)	0	(0.0)	1349	(34.2)	0	(0.0)	2538	(32.9)	0	(0.0)
Dizziness	13	(0.3)	0	(0.0)	22	(0.6)	0	(0.0)	35	(0.5)	0	(0.0)
Somnolence	11	(0.3)	0	(0.0)	9	(0.2)	0	(0.0)	20	(0.3)	0	(0.0)
Hypoesthesia	4	(0.1)	0	(0.0)	6	(0.2)	0	(0.0)	10	(0.1)	0	(0.0)
Paraesthesia	6	(0.2)	0	(0.0)	4	(0.1)	0	(0.0)	10	(0.1)	0	(0.0)
Balance disorder	1	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	7	(0.1)	0	(0.0)
Neuralgia	1	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)
Head discomfort	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Taste disorder	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Brain fog	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Dizziness postural	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Dysaesthesia	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Dysgeusia	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Migraine	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Movement disorder	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Peroneal nerve palsy	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Tremor	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)

Table 11-2 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Underlying disease											
	No				Yes							
	Total		Serious		Total		Serious					
Sample size	3761				3946				7707			
Number of subjects with ADRs	2938		2		3468		3		6406		5	
incidence proportion of ADRs (%)	78.1		0.1		87.9		0.1		83.1		0.1	
Type of ADR	Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)			
Gastrointestinal disorders	300	(8.0)	1	(0.0)	468	(11.9)	0	(0.0)	768	(10.0)	1	(0.0)
Nausea	162	(4.3)	0	(0.0)	219	(5.5)	0	(0.0)	381	(4.9)	0	(0.0)
Diarrhoea	129	(3.4)	0	(0.0)	228	(5.8)	0	(0.0)	357	(4.6)	0	(0.0)
Abdominal pain	112	(3.0)	0	(0.0)	175	(4.4)	0	(0.0)	287	(3.7)	0	(0.0)
Vomiting	26	(0.7)	0	(0.0)	58	(1.5)	0	(0.0)	84	(1.1)	0	(0.0)
Abdominal pain upper	2	(0.1)	0	(0.0)	9	(0.2)	0	(0.0)	11	(0.1)	0	(0.0)
Abdominal discomfort	3	(0.1)	0	(0.0)	6	(0.2)	0	(0.0)	9	(0.1)	0	(0.0)
Stomatitis	4	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)	9	(0.1)	0	(0.0)
Toothache	1	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	3	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	2	(0.0)	0	(0.0)
Oral pain	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Salivary gland pain	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Cheilitis	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Gingival pain	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Glossodynia	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Melaena	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)
Oral discomfort	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Tongue rough	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Lip blister	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Hypoesthesia oral	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Paraesthesia oral	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Tongue exfoliation	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Oral mucosa erosion	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Loose tooth	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Faeces soft	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Anal incontinence	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Oral mucosal roughening	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)

Table 11-2 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Underlying disease					
	No		Yes		Total	
	Total	Serious	Total	Serious	Total	Serious
Sample size	3761		3946		7707	
Number of subjects with ADRs	2938		3468		6406	
incidence proportion of ADRs (%)	78.1		87.9		83.1	
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
Skin and subcutaneous tissue disorders	62 (1.6)	0 (0.0)	100 (2.5)	0 (0.0)	162 (2.1)	0 (0.0)
Pruritus	38 (1.0)	0 (0.0)	68 (1.7)	0 (0.0)	106 (1.4)	0 (0.0)
Rash	7 (0.2)	0 (0.0)	14 (0.4)	0 (0.0)	21 (0.3)	0 (0.0)
Urticaria	9 (0.2)	0 (0.0)	6 (0.2)	0 (0.0)	15 (0.2)	0 (0.0)
Erythema	3 (0.1)	0 (0.0)	8 (0.2)	0 (0.0)	11 (0.1)	0 (0.0)
Eczema	4 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)	9 (0.1)	0 (0.0)
Blister	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Night sweats	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Pain of skin	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Perioral dermatitis	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Skin tightness	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Skin burning sensation	2 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Dermatitis contact	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Purpura	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Scab	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin discolouration	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin induration	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	10 (0.3)	0 (0.0)	29 (0.7)	0 (0.0)	39 (0.5)	0 (0.0)
Oropharyngeal pain	2 (0.1)	0 (0.0)	11 (0.3)	0 (0.0)	13 (0.2)	0 (0.0)
Rhinorrhoea	4 (0.1)	0 (0.0)	6 (0.2)	0 (0.0)	10 (0.1)	0 (0.0)
Cough	3 (0.1)	0 (0.0)	2 (0.1)	0 (0.0)	5 (0.1)	0 (0.0)
Dyspnoea	1 (0.0)	0 (0.0)	3 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Epistaxis	1 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	3 (0.0)	0 (0.0)
Sneezing	1 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	3 (0.0)	0 (0.0)
Oropharyngeal discomfort	2 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Productive cough	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Yawning	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Nasal congestion	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Upper respiratory tract inflammation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Nasal pruritus	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Metabolism and nutrition disorders	6 (0.2)	0 (0.0)	20 (0.5)	0 (0.0)	26 (0.3)	0 (0.0)
Decreased appetite	6 (0.2)	0 (0.0)	20 (0.5)	0 (0.0)	26 (0.3)	0 (0.0)

Table 11-2 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Underlying disease					
	No		Yes		Total	
	Total	Serious	Total	Serious	Total	Serious
Sample size	3761		3946		7707	
Number of subjects with ADRs	2938	2	3468	3	6406	5
incidence proportion of ADRs (%)	78.1	0.1	87.9	0.1	83.1	0.1
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
Blood and lymphatic system disorders	12 (0.3)	0 (0.0)	9 (0.2)	0 (0.0)	21 (0.3)	0 (0.0)
Lymphadenopathy	10 (0.3)	0 (0.0)	6 (0.2)	0 (0.0)	16 (0.2)	0 (0.0)
Lymph node pain	4 (0.1)	0 (0.0)	3 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Ear and labyrinth disorders	3 (0.1)	0 (0.0)	12 (0.3)	0 (0.0)	15 (0.2)	0 (0.0)
Tinnitus	2 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)	6 (0.1)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	3 (0.1)	0 (0.0)	3 (0.0)	0 (0.0)
Hypacusis	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Eye disorders	7 (0.2)	0 (0.0)	7 (0.2)	1 (0.0)	14 (0.2)	1 (0.0)
Eye pain	3 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Periorbital swelling	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye inflammation	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye irritation	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)
Swelling of eyelid	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vision blurred	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Visual acuity reduced	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid irritation	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eyelid pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vascular disorders	5 (0.1)	0 (0.0)	9 (0.2)	1 (0.0)	14 (0.2)	1 (0.0)
Peripheral coldness	4 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Hypotension	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)

Table 11-2 Incidence of ADRs by selected influential factor

As of Sep 8, 2025

Subjects included in safety analysis

	Underlying disease					
	No		Yes		Total	
	Total	Serious	Total	Serious	Total	Serious
Sample size	3761		3946		7707	
Number of subjects with ADRs	2938		3468		6406	
incidence proportion of ADRs (%)	78.1		87.9		83.1	
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
Infections and infestations	7 (0.2)	0 (0.0)	6 (0.2)	0 (0.0)	13 (0.2)	0 (0.0)
Oral herpes	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis viral	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes virus infection	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Cardiac disorders	6 (0.2)	0 (0.0)	6 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Palpitations	6 (0.2)	0 (0.0)	6 (0.2)	0 (0.0)	12 (0.2)	0 (0.0)
Renal and urinary disorders	2 (0.1)	0 (0.0)	8 (0.2)	0 (0.0)	10 (0.1)	0 (0.0)
Pollakiuria	1 (0.0)	0 (0.0)	3 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Nocturia	1 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	3 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Polyuria	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Investigations	1 (0.0)	0 (0.0)	6 (0.2)	0 (0.0)	7 (0.1)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	3 (0.1)	0 (0.0)	3 (0.0)	0 (0.0)
Heart rate increased	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Psychiatric disorders	3 (0.1)	1 (0.0)	1 (0.0)	0 (0.0)	4 (0.1)	1 (0.0)
Dissociative disorder	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Euphoric mood	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Hallucination	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)
Listless	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heat illness	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)

MedDRA/J (28.0)

Attached Form 12

Survey/study title: Shingrix for Intramuscular Injection, Drug Use Investigation

Number of subjects included in safety analysis	7707			
Safety specification	Serious		Non-serious	
	Number of subjects with ADRs	(Incidence proportion)	Number of subjects with ADRs	(Incidence proportion)
Important potential risks	–		–	
Shock and anaphylaxis*1	0	(0.0%)	55	(0.7%)
Potential Immune-Mediated Disease*2	1	(0.0%)	1	(0.0%)

MedDRA/J (28.0)

If there are multiple events of special interest in the same subject, the events will be adopted and tabulated based on the following priority:

Serious > Non-serious.

*1: Events falling under SMQ “Anaphylactic reaction” and “Hypersensitivity” (narrow) in the attached MedDRA code list

*2: Events falling under “pIMD” in the attached MedDRA code list

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLT, HLT, SOC, PT or L1, L2	Code	Term (Japanese)
Safety specification	Shock and anaphylaxis	28.0	SMQ		SMQ "Anaphylactic reaction" (narrow) and "Hypersensitivity" (narrow)
Safety specification	Shock and anaphylaxis	28.0	PT	10002198	Anaphylactic reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10002199	Anaphylactic shock
Safety specification	Shock and anaphylaxis	28.0	PT	10002216	Anaphylactoid reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10002222	Anaphylaxis treatment
Safety specification	Shock and anaphylaxis	28.0	PT	10002424	Angioedema
Safety specification	Shock and anaphylaxis	28.0	PT	10003036	Application site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10003054	Application site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10003645	Atopy
Safety specification	Shock and anaphylaxis	28.0	PT	10005149	Blepharitis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10005589	Blood immunoglobulin E abnormal
Safety specification	Shock and anaphylaxis	28.0	PT	10005591	Blood immunoglobulin E increased
Safety specification	Shock and anaphylaxis	28.0	PT	10006404	Bromoderma
Safety specification	Shock and anaphylaxis	28.0	PT	10006482	Bronchospasm
Safety specification	Shock and anaphylaxis	28.0	PT	10009192	Circulatory collapse
Safety specification	Shock and anaphylaxis	28.0	PT	10010726	Conjunctival oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10010744	Conjunctivitis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10010836	Contrast media reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10011033	Corneal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10011411	Cross-sensitivity reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10011686	Cutaneous vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10012431	Dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10012432	Dermatitis acneiform
Safety specification	Shock and anaphylaxis	28.0	PT	10012434	Dermatitis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10012438	Dermatitis atopic
Safety specification	Shock and anaphylaxis	28.0	PT	10012441	Dermatitis bullous
Safety specification	Shock and anaphylaxis	28.0	PT	10012442	Dermatitis contact
Safety specification	Shock and anaphylaxis	28.0	PT	10012455	Dermatitis exfoliative
Safety specification	Shock and anaphylaxis	28.0	PT	10012456	Dermatitis exfoliative generalised
Safety specification	Shock and anaphylaxis	28.0	PT	10012468	Dermatitis herpetiformis
Safety specification	Shock and anaphylaxis	28.0	PT	10012470	Dermatitis infected
Safety specification	Shock and anaphylaxis	28.0	PT	10013687	Drug eruption
Safety specification	Shock and anaphylaxis	28.0	PT	10013700	Drug hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10014184	Eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10014198	Eczema infantile
Safety specification	Shock and anaphylaxis	28.0	PT	10014201	Eczema nummular
Safety specification	Shock and anaphylaxis	28.0	PT	10014627	Encephalopathy allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10014989	Epididymolysis bullosa
Safety specification	Shock and anaphylaxis	28.0	PT	10015029	Epiglottic oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10015218	Erythema multiforme
Safety specification	Shock and anaphylaxis	28.0	PT	10015226	Erythema nodosum
Safety specification	Shock and anaphylaxis	28.0	PT	10015907	Eye allergy
Safety specification	Shock and anaphylaxis	28.0	PT	10015967	Eye swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10015993	Eyelid oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10016029	Face oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10016741	Fixed eruption
Safety specification	Shock and anaphylaxis	28.0	PT	10018258	Giant papillary conjunctivitis
Safety specification	Shock and anaphylaxis	28.0	PT	10018291	Gingival swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10019617	Henoch-Schönlein purpura
Safety specification	Shock and anaphylaxis	28.0	PT	10020751	Hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10020764	Hypersensitivity vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10021247	Idiopathic urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10022056	Injection site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10022071	Injection site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10022094	Injection site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10022107	Injection site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10023845	Laryngeal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10023891	Laryngospasm
Safety specification	Shock and anaphylaxis	28.0	PT	10023893	Laryngotracheal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10024558	Lip oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10024570	Lip swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10028164	Multiple allergies
Safety specification	Shock and anaphylaxis	28.0	PT	10029120	Nephritis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10030081	Oculomucocutaneous syndrome
Safety specification	Shock and anaphylaxis	28.0	PT	10030110	Oedema mouth
Safety specification	Shock and anaphylaxis	28.0	PT	10031111	Oropharyngeal spasm
Safety specification	Shock and anaphylaxis	28.0	PT	10031118	Oropharyngeal swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10034541	Perioral dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10034545	Periorbital oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10034829	Pharyngeal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10037789	Radioallergosorbent test positive
Safety specification	Shock and anaphylaxis	28.0	PT	10037844	Rash
Safety specification	Shock and anaphylaxis	28.0	PT	10037855	Rash erythematous
Safety specification	Shock and anaphylaxis	28.0	PT	10037857	Rash follicular
Safety specification	Shock and anaphylaxis	28.0	PT	10037867	Rash macular
Safety specification	Shock and anaphylaxis	28.0	PT	10037868	Rash maculo-papular
Safety specification	Shock and anaphylaxis	28.0	PT	10037870	Rash morbilliform
Safety specification	Shock and anaphylaxis	28.0	PT	10037871	Rash neonatal
Safety specification	Shock and anaphylaxis	28.0	PT	10037876	Rash papular
Safety specification	Shock and anaphylaxis	28.0	PT	10037879	Rash papulosquamous
Safety specification	Shock and anaphylaxis	28.0	PT	10037884	Rash pruritic
Safety specification	Shock and anaphylaxis	28.0	PT	10037888	Rash pustular
Safety specification	Shock and anaphylaxis	28.0	PT	10037890	Rash scarlatiniform
Safety specification	Shock and anaphylaxis	28.0	PT	10037898	Rash vesicular
Safety specification	Shock and anaphylaxis	28.0	PT	10037973	Reaction to azo-dyes
Safety specification	Shock and anaphylaxis	28.0	PT	10037974	Reaction to colouring
Safety specification	Shock and anaphylaxis	28.0	PT	10037977	Reaction to food additive
Safety specification	Shock and anaphylaxis	28.0	PT	10039085	Rhinitis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10039755	Scrotal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10040400	Serum sickness

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or LJT	Code	Term (Japanese)
Safety specification	Shock and anaphylaxis	28.0	PT	10040402	Serum sickness-like reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10040560	Shock
Safety specification	Shock and anaphylaxis	28.0	PT	10040581	Shock symptom
Safety specification	Shock and anaphylaxis	28.0	PT	10040893	Skin necrosis
Safety specification	Shock and anaphylaxis	28.0	PT	10040934	Skin test positive
Safety specification	Shock and anaphylaxis	28.0	PT	10041307	Solar urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10041316	Solvent sensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10042033	Stevens-Johnson syndrome
Safety specification	Shock and anaphylaxis	28.0	PT	10042682	Swelling face
Safety specification	Shock and anaphylaxis	28.0	PT	10042690	Swelling of eyelid
Safety specification	Shock and anaphylaxis	28.0	PT	10042727	Swollen tongue
Safety specification	Shock and anaphylaxis	28.0	PT	10043967	Tongue oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10044223	Toxic epidermal necrolysis
Safety specification	Shock and anaphylaxis	28.0	PT	10044296	Tracheal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10045240	Type I hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10046735	Urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10046740	Urticaria cholinergic
Safety specification	Shock and anaphylaxis	28.0	PT	10046742	Urticaria contact
Safety specification	Shock and anaphylaxis	28.0	PT	10046750	Urticaria papular
Safety specification	Shock and anaphylaxis	28.0	PT	10046751	Urticaria physical
Safety specification	Shock and anaphylaxis	28.0	PT	10046752	Urticaria pigmentosa
Safety specification	Shock and anaphylaxis	28.0	PT	10046755	Urticaria vesiculosa
Safety specification	Shock and anaphylaxis	28.0	PT	10046943	Vaginal ulceration
Safety specification	Shock and anaphylaxis	28.0	PT	10047111	Vasculitic rash
Safety specification	Shock and anaphylaxis	28.0	PT	10047768	Vulval ulceration
Safety specification	Shock and anaphylaxis	28.0	PT	10048799	Acute generalised exanthematous pustulosis
Safety specification	Shock and anaphylaxis	28.0	PT	10048820	Urticarial vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10049153	Allergic sinusitis
Safety specification	Shock and anaphylaxis	28.0	PT	10049305	Gingival oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10050004	Rash maculovesicular
Safety specification	Shock and anaphylaxis	28.0	PT	10050099	Application site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10050104	Application site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10050181	Vulvovaginal ulceration
Safety specification	Shock and anaphylaxis	28.0	PT	10050639	Allergic pharyngitis
Safety specification	Shock and anaphylaxis	28.0	PT	10050894	Anti-neutrophil cytoplasmic antibody positive vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10051126	Scleritis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10051394	Allergic cystitis
Safety specification	Shock and anaphylaxis	28.0	PT	10051792	Infusion related reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10052098	Iodine allergy
Safety specification	Shock and anaphylaxis	28.0	PT	10052139	Eye oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10052250	Circumoral oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10052271	Catheter site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10052272	Catheter site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10052568	Urticaria chronic
Safety specification	Shock and anaphylaxis	28.0	PT	10052613	Allergic bronchitis
Safety specification	Shock and anaphylaxis	28.0	PT	10053177	Epidermolysis
Safety specification	Shock and anaphylaxis	28.0	PT	10053613	Type IV hypersensitivity reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10053614	Type III immune complex mediated reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10053779	Allergic cough
Safety specification	Shock and anaphylaxis	28.0	PT	10054000	Type II hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10055048	Allergy to vaccine
Safety specification	Shock and anaphylaxis	28.0	PT	10055182	Eczema weeping
Safety specification	Shock and anaphylaxis	28.0	PT	10056352	Allergy test positive
Safety specification	Shock and anaphylaxis	28.0	PT	10056387	Encephalitis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10056647	Periorbital swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10056671	Mucocutaneous rash
Safety specification	Shock and anaphylaxis	28.0	PT	10056872	Palpable purpura
Safety specification	Shock and anaphylaxis	28.0	PT	10056998	Palatal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10057380	Allergic keratitis
Safety specification	Shock and anaphylaxis	28.0	PT	10057431	Scleral oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10057970	Toxic skin eruption
Safety specification	Shock and anaphylaxis	28.0	PT	10057984	Rash rubelliform
Safety specification	Shock and anaphylaxis	28.0	PT	10058675	Dermatitis psoriasiform
Safety specification	Shock and anaphylaxis	28.0	PT	10058681	Eczema vesicular
Safety specification	Shock and anaphylaxis	28.0	PT	10058898	Hand dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10059071	Stoma site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10059284	Epidermal necrosis
Safety specification	Shock and anaphylaxis	28.0	PT	10059447	Allergic colitis
Safety specification	Shock and anaphylaxis	28.0	PT	10059499	Haemorrhagic urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10059830	Infusion site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10060934	Allergic oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10061430	Arthritis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10061557	Allergic otitis media
Safety specification	Shock and anaphylaxis	28.0	PT	10062506	Heparin-induced thrombocytopenia
Safety specification	Shock and anaphylaxis	28.0	PT	10062918	Dennie-Morgan fold
Safety specification	Shock and anaphylaxis	28.0	PT	10063119	Anaphylactoid shock
Safety specification	Shock and anaphylaxis	28.0	PT	10063438	Pruritus allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10063527	Allergic respiratory symptom
Safety specification	Shock and anaphylaxis	28.0	PT	10063532	Allergic respiratory disease
Safety specification	Shock and anaphylaxis	28.0	PT	10063683	Application site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10063786	Implant site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10063787	Implant site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10063855	Implant site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10063858	Implant site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10064059	Antiallergic therapy
Safety specification	Shock and anaphylaxis	28.0	PT	10064579	Exfoliative rash

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or LJT	Code	Term (Japanese)
Safety specification	Shock and anaphylaxis	28.0	PT	10064788	Reaction to preservatives
Safety specification	Shock and anaphylaxis	28.0	PT	10064866	Laryngitis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10065458	Infusion site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10065471	Infusion site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10065490	Infusion site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10065514	Antidromysial antibody positive
Safety specification	Shock and anaphylaxis	28.0	PT	10066042	Eczema vaccinatum
Safety specification	Shock and anaphylaxis	28.0	PT	10066173	Allergic transfusion reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10066221	Injection site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10066273	Vulval eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10066797	Injection site recall reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10066837	Gleich's syndrome
Safety specification	Shock and anaphylaxis	28.0	PT	10066973	Contrast media allergy
Safety specification	Shock and anaphylaxis	28.0	PT	10067113	Anaphylactic transfusion reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10067142	Immediate post-injection reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10067317	Oculo-respiratory syndrome
Safety specification	Shock and anaphylaxis	28.0	PT	10067510	Contact stomatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10067950	Oropharyngeal blistering
Safety specification	Shock and anaphylaxis	28.0	PT	10067972	Interstitial granulomatous dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10067995	Injection site vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10068355	Oral allergic syndrome
Safety specification	Shock and anaphylaxis	28.0	PT	10068809	Palisaded neutrophilic granulomatous dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10068880	Vaccination site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10069167	Koebner's syndrome
Safety specification	Shock and anaphylaxis	28.0	PT	10069440	Henoch-Schönlein purpura nephritis
Safety specification	Shock and anaphylaxis	28.0	PT	10069477	Vaccination site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10069482	Vaccination site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10069489	Vaccination site exfoliation
Safety specification	Shock and anaphylaxis	28.0	PT	10069622	Vaccination site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10069623	Vaccination site vesicles
Safety specification	Shock and anaphylaxis	28.0	PT	10069773	Administration related reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10070492	Limbal swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10070559	Distributive shock
Safety specification	Shock and anaphylaxis	28.0	PT	10070581	Immune tolerance induction
Safety specification	Shock and anaphylaxis	28.0	PT	10071152	Injection related reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10071156	Administration site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10071198	Allergic hepatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10071380	Chronic hyperplastic eosinophilic sinusitis
Safety specification	Shock and anaphylaxis	28.0	PT	10071399	Chronic eosinophilic rhinosinusitis
Safety specification	Shock and anaphylaxis	28.0	PT	10071588	Vulvovaginal rash
Safety specification	Shock and anaphylaxis	28.0	PT	10072867	Device allergy
Safety specification	Shock and anaphylaxis	28.0	PT	10073168	Incision site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10073411	Incision site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10073508	Drug reaction with eosinophilia and systemic symptoms
Safety specification	Shock and anaphylaxis	28.0	PT	10073612	Instillation site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10073622	Instillation site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10073627	Instillation site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10073992	Catheter site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10073995	Catheter site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10073998	Catheter site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10074014	Catheter site vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10074079	Allergy to immunoglobulin therapy
Safety specification	Shock and anaphylaxis	28.0	PT	10074332	Paternal reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10074350	Drug provocation test
Safety specification	Shock and anaphylaxis	28.0	PT	10074403	Palatal swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10074509	Stoma site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10074850	Infusion site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10074851	Infusion site vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10075072	Allergic otitis externa
Safety specification	Shock and anaphylaxis	28.0	PT	10075096	Administration site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10075099	Administration site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10075102	Administration site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10075109	Administration site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10075185	Allergic eosinophilia
Safety specification	Shock and anaphylaxis	28.0	PT	10075203	Mouth swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10075217	Mast cell activation syndrome
Safety specification	Shock and anaphylaxis	28.0	PT	10075308	Allergic gastroenteritis
Safety specification	Shock and anaphylaxis	28.0	PT	10075479	Allergy alert test positive
Safety specification	Shock and anaphylaxis	28.0	PT	10075572	Medical device site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10075575	Medical device site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10075579	Medical device site hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10075585	Medical device site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10075588	Medical device site urticaria
Safety specification	Shock and anaphylaxis	28.0	PT	10075807	Nodular rash
Safety specification	Shock and anaphylaxis	28.0	PT	10075964	Administration site recall reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10075969	Administration site vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10076024	Application site recall reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10076027	Application site vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10076085	Infusion site recall reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10076140	Medical device site recall reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10076161	Vaccination site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10076188	Vaccination site recall reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10076191	Vaccination site vasculitis
Safety specification	Shock and anaphylaxis	28.0	PT	10076229	Intestinal angioedema
Safety specification	Shock and anaphylaxis	28.0	PT	10076470	Documented hypersensitivity to administered product
Safety specification	Shock and anaphylaxis	28.0	PT	10076606	Mast cell degranulation present
Safety specification	Shock and anaphylaxis	28.0	PT	10076665	Dialysis membrane reaction

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLT, HLT, SOC, PT or L1,T	Code	Term (Japanese)
Safety specification	Shock and anaphylaxis	28.0	PT	10077117	Vessel puncture site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10077279	Allergy to surgical sutures
Safety specification	Shock and anaphylaxis	28.0	PT	10077813	Vessel puncture site vesicles
Safety specification	Shock and anaphylaxis	28.0	PT	10078117	Eosinophilic granulomatosis with polyangitis
Safety specification	Shock and anaphylaxis	28.0	PT	10078325	Symmetrical drug-related intertriginous and flexural exanthema
Safety specification	Shock and anaphylaxis	28.0	PT	10078682	Anal eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10078783	Oropharyngeal oedema
Safety specification	Shock and anaphylaxis	28.0	PT	10078853	Allergic reaction to excipient
Safety specification	Shock and anaphylaxis	28.0	PT	10079554	Allergic stomatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10079925	Reaction to excipient
Safety specification	Shock and anaphylaxis	28.0	PT	10080783	Vulvovaginitis allergic
Safety specification	Shock and anaphylaxis	28.0	PT	10080894	Procedural shock
Safety specification	Shock and anaphylaxis	28.0	PT	10081000	Vernal keratoconjunctivitis
Safety specification	Shock and anaphylaxis	28.0	PT	10081004	Hypersensitivity myocarditis
Safety specification	Shock and anaphylaxis	28.0	PT	10081035	Acquired C1 inhibitor deficiency
Safety specification	Shock and anaphylaxis	28.0	PT	10081492	Atopic cough
Safety specification	Shock and anaphylaxis	28.0	PT	10081703	Circumoral swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10081988	Hypersensitivity pneumonitis
Safety specification	Shock and anaphylaxis	28.0	PT	10082270	Pharyngeal swelling
Safety specification	Shock and anaphylaxis	28.0	PT	10082290	Urticarial dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10082681	Reaction to flavouring
Safety specification	Shock and anaphylaxis	28.0	PT	10082742	Infusion related hypersensitivity reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10083164	SIS-TEN overlap
Safety specification	Shock and anaphylaxis	28.0	PT	10083260	Scrotal dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10083809	Bullous haemorrhagic dermatosis
Safety specification	Shock and anaphylaxis	28.0	PT	10083842	Immune thrombocytopenia
Safety specification	Shock and anaphylaxis	28.0	PT	10084049	Nutritional supplement allergy
Safety specification	Shock and anaphylaxis	28.0	PT	10084905	Generalised bullous fixed drug eruption
Safety specification	Shock and anaphylaxis	28.0	PT	10085938	Vascular access site dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10085939	Vascular access site eczema
Safety specification	Shock and anaphylaxis	28.0	PT	10086007	Allergic lymphangitis
Safety specification	Shock and anaphylaxis	28.0	PT	10086347	Polymers allergy
Safety specification	Shock and anaphylaxis	28.0	PT	10086454	Reaction to sweetener
Safety specification	Shock and anaphylaxis	28.0	PT	10086476	Dermal filler reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10086737	Vancomycin infusion reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10087203	Periorbital dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10087325	Bone cement allergy
Safety specification	Shock and anaphylaxis	28.0	PT	10087419	Penile dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10087423	NSAID exacerbated respiratory disease
Safety specification	Shock and anaphylaxis	28.0	PT	10087549	Tattoo associated skin reaction
Safety specification	Shock and anaphylaxis	28.0	PT	10087940	Puncture site rash
Safety specification	Shock and anaphylaxis	28.0	PT	10087943	Systemic contact dermatitis
Safety specification	Shock and anaphylaxis	28.0	PT	10089003	AGEP-DRESS overlap
Safety specification	Shock and anaphylaxis	28.0	PT	10089091	Multiple drug hypersensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10089389	Chlorine sensitivity
Safety specification	Shock and anaphylaxis	28.0	PT	10091102	Nikolsky's sign positive
Safety specification	Shock and anaphylaxis	28.0	PT	10091872	Eczematous cheilitis
Safety specification	Shock and anaphylaxis	28.0	PT	10092061	Periorbital eczema
Safety specification	Potential immune-mediated disease (pIMD)	28.0	SMQ		SMQ "Immune-mediated/Autoimmune Disorders" (broad) and "Demyelination" (broad)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10000606	Acrosclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10000709	Acute disseminated encephalomyelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10000748	Acute febrile neutrophilic dermatosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10001130	Addison's disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10001761	Alopecia areata
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10001881	Alveolar proteinosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002022	Amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002556	Ankylosing spondylitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002653	Anosmia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002799	Antimitochondrial antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002817	Antiphospholipid syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002921	Aortitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002965	Aplasia pure red cell
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10002967	Aplastic anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10003230	Arteritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10003232	Arteritis coronary
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10003246	Arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10003253	Arthritis enteropathic
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10003827	Autoimmune hepatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10003840	Autonomic nervous system imbalance
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10003882	Axonal neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10004213	Behcet's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10004223	Bell's palsy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10006542	Bulbar palsy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10007509	Cardiac amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10007604	Cardiac sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10007630	Cardiolipin antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10008087	Cerebral arteritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10008609	Cholangitis sclerosing
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10008882	Chronic gastritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10009839	Celiac disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10009854	Cold agglutinins positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10009868	Cold type haemolytic anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10009887	Colitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10009900	Colitis ulcerative

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or L1, L2	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10009903	Collagen disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10009905	Collagen-vascular disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10010252	Concentric sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10010941	Coombs positive haemolytic anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011314	Cranial nerve palsies multiple
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011380	CREST syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011401	Crohn's disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011474	Cryoglobulinaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011562	CSF oligoclonal band present
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011659	Cutaneous amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011674	Cutaneous sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011686	Cutaneous vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10011796	Cystitis interstitial
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012305	Demyelination
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012431	Dermatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012441	Dermatitis bullous
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012468	Dermatitis herpetiformis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012503	Dermatomyositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012601	Diabetes mellitus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012671	Diabetic ketoacidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10012978	Diffuse vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10013637	Dressler's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014581	Encephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014589	Encephalitis haemorrhagic
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014602	Encephalitis post immunisation
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014619	Encephalomyelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014625	Encephalopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014695	Endocrine disorders
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014866	Enteritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014893	Enterocolitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10014954	Eosinophilic fasciitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10015213	Erythema induratum
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10015218	Erythema multiforme
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10015226	Erythema nodosum
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10016062	Facial paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10016386	Felty's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10017853	Gastritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018250	Giant cell arteritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018364	Glomerulonephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018370	Glomerulonephritis membranoproliferative
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018372	Glomerulonephritis membranous
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018378	Glomerulonephritis rapidly progressive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018620	Goodpasture's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018706	Graves' disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018767	Guillain-Barre syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10018916	Haemolytic anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10019617	Henoch-Schonlein purpura
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10019717	Hepatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10020631	Hypergammaglobulinaemia benign monoclonal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10020850	Hyperthyroidism
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10020983	Hypogammaglobulinaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10021041	Hypoparathyroidism
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10021114	Hypothyroidism
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10021240	Idiopathic pulmonary fibrosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10021263	IgA nephropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10021283	IIIrd nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10021497	Immunoglobulins abnormal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10021972	Inflammatory bowel disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10022472	Insulin autoimmune syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10022611	Interstitial lung disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10022852	Intrinsic factor antibody abnormal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10022855	Intrinsic factor antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10023110	IVth nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10023320	Kawasaki's disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10023358	Keratoderma blenorrhagica
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10024062	LE cells present
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10024382	Leukoencephalopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10024429	Lichen planus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10024434	Lichen sclerosus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10024515	Linear IgA disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10025129	Lupoid hepatic cirrhosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10025130	Lupus encephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10025140	Lupus nephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10026828	Marchiafava-Bignami disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10027201	Meningitis aseptic
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10027754	Mixed connective tissue disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10027910	Mononeuritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10027918	Mononeuropathy multiplex
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10027982	Morphoea
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028245	Multiple sclerosis

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or L1, T	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028365	Muscular sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028417	Myasthenia gravis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028419	Myasthenia gravis neonatal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028424	Myasthenic syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028524	Myelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028527	Myelitis transverse
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028606	Myocarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028632	Myokymia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028650	Myopericarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028653	Myositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10028713	Narcolepsy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10029117	Nephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10029229	Neuralgic amyotrophy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10029240	Neuritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10029244	Neuritis cranial
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10029331	Neuropathy peripheral
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10029491	Nodular vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10030069	Oculofacial paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10030136	Oesophageal achalasia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10030942	Optic neuritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10030983	Oral lichen planus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10033534	Palindromic rheumatism
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10033554	Palmoplantar keratoderma
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10033645	Pancreatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10033996	Parietal cell antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10034277	Pemphigoid
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10034280	Pemphigus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10034484	Pericarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10034580	Peripheral motor neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10034620	Peripheral sensory neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10034695	Pernicious anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10035742	Pneumonitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036024	Polysarthritis nodosa
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036072	Polyglandular autoimmune syndrome type I
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036073	Polyglandular autoimmune syndrome type II
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036074	Polyglandular disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036099	Polymyalgia rheumatica
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036102	Polymyositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036111	Polynuropathy idiopathic progressive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036601	Premature menopause
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036673	Primary amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036783	Proctitis ulcerative
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10036807	Progressive multifocal leukoencephalopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037153	Psoriasis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037162	Psoriatic arthropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037383	Pulmonary fibrosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037430	Pulmonary sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037457	Pulmonary vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037575	Pustular psoriasis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037635	Pyoderma gangrenosum
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037778	Radiculitis brachial
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10037912	Raynaud's phenomenon
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10038357	Renal amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10038373	Renal arteritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10038546	Renal vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10038905	Retinal vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10038910	Retinitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10038923	Retinopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10038979	Retroperitoneal fibrosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039073	Rheumatoid arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039080	Rheumatoid factor positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039081	Rheumatoid lung
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039486	Sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039705	Scleritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039710	Scleroderma

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or L1, L2	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039714	Scleroderma-like reaction
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10039811	Secondary amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10040633	Sicca syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10040767	Sjogren's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10040968	SLE arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10041229	Smooth muscle antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10042033	Stevens-Johnson syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10042061	Sjill's disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10042276	Subacute endocarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10042742	Sympathetic ophthalmia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10042945	Systemic Lupus Erythematosus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10042946	Systemic lupus erythematosus rash
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10042954	Systemic sclerosis pulmonary
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043097	Takayasu's arteritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043280	Terminal ileitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043540	Thromboangiitis obliterans
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043554	Thrombocytopenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043561	Thrombocytopenic purpura
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043648	Thrombotic thrombocytopenic purpura
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043709	Thyroid disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10043778	Thyroiditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10044223	Toxic epidermal necrolysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10044652	Trigeminal neuralgia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10046851	Uveitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10047097	Vascular purpura
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10047111	Vasculitic rash
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10047115	Vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10047124	Vasculitis necrotising
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10047641	VIIth nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10047642	Vitiligo
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10047674	Vocal cord paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048319	Vasculitis gastrointestinal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048393	Multiple sclerosis relapse
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048628	Rheumatoid vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048678	Antiphospholipid antibodies positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048694	Rheumatoid nodule
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048799	Acute generalised exanthematous pustulosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048820	Urticarial vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048842	XIIth nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048895	Pythiasis lichenoides et varioliformis acuta
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048997	Encephalitis brain stem
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10048999	Leukoencephalomyelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049020	Encephalitis periaxialis diffusa
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049046	Autoimmune thyroiditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049144	Antiacyetylcholine receptor antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049168	Ocular myasthenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049234	Vocal cord paresis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049411	Anti-prothrombin antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049439	Anti-islet cell antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049567	Miller Fisher syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049690	Lhermitte's sign
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10049788	Trigeminal palsy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10050551	Lupus-like syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10050685	Cytokine storm
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10050894	Anti-neutrophil cytoplasmic antibody positive vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10050981	Complement factor C3 decreased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10050983	Complement factor C4 decreased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051222	Toxic oil syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051229	Cryofibrinogenemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051265	Spondyloarthropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051267	Facial paresis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051270	Glossopharyngeal nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051316	SAPHO syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051552	Complement factor C1 decreased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10051555	Complement factor C2 decreased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10052015	Cytokine release syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10052801	Pemphigoid gestationis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053291	Rheumatoid nodule removal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053395	Progressive multiple sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053614	Type III immune complex mediated reaction
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053814	Anti-insulin antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053815	Anti-insulin antibody increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053833	Histone antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053869	POEMS syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053872	MELAS syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10053873	Evans syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10054201	IVth nerve paresis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10054202	IIIrd nerve paresis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10055128	Autoimmune neutropenia

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or L1, L2	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056332	Panencephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056387	Encephalitis allergic
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056509	Cutaneous lupus erythematosus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056667	Cogan's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056673	Peripheral sensorimotor neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056872	Palpable purpura
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056954	Gottson's papules
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10056979	Colitis microscopic
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057108	Anti-erythrocyte antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057481	Lupus pneumonitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057645	Chronic inflammatory demyelinating polyradiculoneuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057887	Neonatal lupus erythematosus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057903	Subacute cutaneous lupus erythematosus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057928	Acute cutaneous lupus erythematosus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057929	Chronic cutaneous lupus erythematosus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10057962	Rheumatoid factor increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10058143	Lupus vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10058149	Pericarditis lupus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10058225	Lupus endocarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10058358	Colitis erosive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10058529	Anti-platelet antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10058994	Acute haemorrhagic leukoencephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10059176	Juvenile idiopathic arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10059250	Gastrointestinal amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10059483	Postpericardiotomy syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10059669	Laryngeal rheumatoid arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10059728	Anti-GAD antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10059730	Anti-GAD antibody negative
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060055	Antinuclear antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060107	Liver-kidney microsomal antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060136	Antineutrophil cytoplasmic antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060138	Antineutrophil cytoplasmic antibody increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060234	Rheumatoid factor quantitative increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060310	Anti-thyroid antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060742	Endocrine ophthalmopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10060973	Autoantibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061047	Complement factor abnormal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061048	Complement factor decreased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061093	Cranial nerve disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061110	DNA antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061323	Optic neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061371	Spondylitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061664	Autoimmune disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061811	Demyelinating polyneuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061908	Cranial nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10061911	Paresis cranial nerve
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10062506	Heparin-induced thrombocytopenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10062553	Scleroderma renal crisis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10062758	Myasthenia gravis crisis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10062876	Antigliadin antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10062898	Peritonitis lupus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10062940	Neuropathy, ataxia, retinitis pigmentosa syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063344	Microscopic polyangiitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063399	Relapsing-remitting multiple sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063400	Secondary progressive multiple sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063401	Primary progressive multiple sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063420	Loeffgren syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063663	Neuropsychiatric lupus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063685	Lymphocytic hypophysitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10063945	Pulmonary amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064000	Lichenoid keratosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064115	Polyglandular autoimmune syndrome type III
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064212	Eosinophilic oesophagitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064539	Autoimmune myocarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064553	Dialysis amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064554	Amyloid arthropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064661	Vagus nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064726	Antinuclear antibody increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064865	Anti-sperm antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10064996	Ulcerative keratitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065159	Polychondritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065513	Anti-glomerular basement membrane antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065515	Antimycardial antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065579	Multifocal motor neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065580	Lewis-Sumner syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065700	Ocular sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065917	Caplan's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065919	Tongue amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10065996	Autoimmune inner ear disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10066389	Latent autoimmune diabetes in adults
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10066391	Lupus myocarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10066404	Beta-2 glycoprotein antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10066407	Inclusion body myositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10066453	Mesangioproliferative glomerulonephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10066926	Ocular vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067063	Progressive relapsing multiple sclerosis

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or L1, T	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067067	Marburg's variant multiple sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067129	Hypoglossal nerve paresis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067427	Rheumatoid scleritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067485	Uhthoff's phenomenon
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067527	Segmented hyalinising vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067584	Type 1 diabetes mellitus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067657	Systemic lupus erythematosus disease activity index increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067658	Systemic lupus erythematosus disease activity index decreased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067659	Systemic lupus erythematosus disease activity index abnormal
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067737	Lupus hepatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067738	Lupus enteritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067739	Shrinking lung syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067750	Lupus pancreatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067776	Ocular pemphigoid
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067873	Hashitoxicosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067972	Interstital granulomatous dermatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067982	Butterfly rash
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10067995	Injection site vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068008	Trigeminal nerve paresis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068044	Cerebral amyloid angiopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068225	Anti-insulin receptor antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068226	Anti-insulin receptor antibody increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068279	Fibrillary glomerulonephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068406	Capillaritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068513	Pulmonary renal syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068664	Liver sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068786	Overlap syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068798	Anti-cyclic citrullinated peptide antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068801	Antisynthetase syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068809	Palisaded neutrophilic granulomatous dermatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10068828	Marine Lenhart syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069002	Autoimmune pancreatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069034	Tubulointerstitial nephritis and uveitis syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069197	Yellow fever vaccine-associated viscerotropic disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069198	Yellow fever vaccine-associated neurotropic disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069350	Osmotic demyelination syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069432	Hashimoto's encephalopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069440	Henoch-Schönlein purpura nephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069450	Hypoglossal nerve paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069509	Autoimmune pancytopenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069521	Autoimmune lymphoproliferative syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069825	Myoclonic epilepsy and ragged-red fibres
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069907	Double stranded DNA antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10069910	Antiribosomal P antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070356	JC polyomavirus test positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070439	Autoimmune neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070495	Multiple sclerosis relapse prophylaxis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070579	Satoyoshi syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070714	Band sensation
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070716	Multiple sclerosis pseudo relapse
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070949	Metastatic cutaneous Crohn's disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10070953	Reynold's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071044	Vib nerve paresis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071066	Posterior reversible encephalopathy syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071068	Clinically isolated syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071141	Rasmussen encephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071155	Autoimmune arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071252	Haemorrhagic vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071282	Mastocytic enterocolitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071384	Expanded disability status scale score increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071385	Expanded disability status scale score decreased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071389	Thyroid stimulating immunoglobulin increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071400	Axial spondyloarthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071530	Chronic recurrent multifocal osteomyelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071573	Susac's syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071574	Testicular autoimmunity
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071575	Undifferentiated connective tissue disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071576	Autoimmune aplastic anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071577	Autoimmune hyperlipidaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071578	Autoimmune retinopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071579	Neuronal neuropathy

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or LJT	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071583	Haemophagocytic lymphohistiocytosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10071764	Noninfectious myelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072134	Anti-transglutaminase antibody increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072148	Stiff person syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072220	Autoinflammatory disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072362	Rheumatoid neutrophilic dermatosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072378	Encephalitis autoimmune
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072498	Anti-IA2 antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072500	Anti-NMDA antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072502	Anti-VGCC antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072504	Anti-VGCC antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072506	Anti-actin antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072508	Anti-aquaporin-4 antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072510	Anti-basal ganglia antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072512	Anti-epithelial antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072514	Anti-exosome complex antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072516	Anti-ganglioside antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072519	Anti-glycyl-tRNA synthetase antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072522	Anti-muscle specific kinase antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072524	Anti-neuronal antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072528	Anti-vimentin antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072530	Anti-zinc transporter 8 antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072535	Thromboplastin antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072579	Granulomatosis with polyangiitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072628	Fulminant type 1 diabetes mellitus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072736	Rheumatic disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072757	Chronic spontaneous urticaria
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072887	Anti-interferon antibody negative
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072888	Anti-interferon antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10072959	Birdshot chorioretinopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10073006	Progressive facial hemiatrophy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10073016	Chronic autoimmune glomerulonephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10073229	Scleroderma associated digital ulcer
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10073694	Lupus pleurisy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10073785	Autoimmune haemolytic anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10073929	IRVAN syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074068	Pyostomatitis vegetans
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074436	Noninfective oophoritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074517	Stoma site vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074712	Noninfective encephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074713	Noninfective encephalomyelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074714	Lupus cystitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074929	Digital pitting scar
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074943	Secondary cerebellar degeneration
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10074954	Granulomatous dermatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075006	Morvan syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075197	Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075251	Hepatic amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075528	Toxic leukoencephalopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075688	Autoimmune demyelinating disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075689	Autoimmune dermatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075690	Autoimmune uveitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075691	Autoimmune encephalopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075714	Vasculitic ulcer
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075761	Autoimmune colitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10075969	Administration site vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076027	Application site vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076191	Vaccination site vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076328	Central nervous system lupus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076549	Enteropathic spondylitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076644	Autoimmune hypothyroidism
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076657	Acute motor-sensory axonal neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076658	Acute motor axonal neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076673	Juvenile polymyositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076674	Juvenile psoriatic arthritis

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or L1T	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076675	Juvenile spondylarthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10076985	Bickerstaff's encephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10077087	Autoimmune nephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10077172	Atrophic thyroiditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10077209	IgM nephropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10077271	Immunoglobulin G4 related disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10077665	Immune-mediated adverse reaction
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10077827	C3 glomerulopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10077875	Neuromyelitis optica spectrum disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078011	Neurosarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078117	Eosinophilic granulomatosis with polyangiitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078132	MAGIC syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078268	Idiopathic interstitial pneumonia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078318	Anti-myelin-associated glycoprotein antibodies positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078324	Anti-myelin-associated glycoprotein associated polyneuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078371	Anti-saccharomyces cerevisiae antibody test positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078556	Tumefactive multiple sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078638	Systemic scleroderma
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078856	Anti-SRP antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078953	Autoimmune endocrine disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078957	JC virus CSF test positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078961	Immune-mediated enterocolitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078962	Immune-mediated hepatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078963	Immune-mediated neuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10078964	Immune-mediated endocrinopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10079012	Silent thyroiditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10079058	Autoimmune pericarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10079165	Autoimmune thyroid disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10079292	RIS
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10079359	Stiff leg syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10079411	Rheumatic brain disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10079642	Lupus myositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080243	Autoimmune anaemia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080353	Neuromyelitis optica pseudo relapse
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080429	Primary biliary cholangitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080512	Anti-HLA antibody test positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080576	Alloimmune hepatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080631	IPeX syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080700	Relapsing multiple sclerosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10080701	Autoimmune lung disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081046	Zika virus associated Guillain Barre syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081123	Autoimmune eye disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081142	Lichen planopilaris
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081456	Autoimmune enteropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081461	CIq nephropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081726	Subacute inflammatory demyelinating polyneuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081778	Central nervous system vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10081981	Anti-glomerular basement membrane disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10082001	Vogt-Koyanagi-Harada disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10082097	Acute flaccid myelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10082283	Anti-RNA polymerase III antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10082418	Autoimmune myositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10082606	Immune-mediated myocarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083004	Immune-mediated pancytopenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083069	Immune-mediated uveitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083070	Immune-mediated nephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083071	Immune-mediated thyroiditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083072	Immune-mediated pancreatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083073	Immune-mediated myositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083074	Immune-mediated encephalitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083075	Immune-mediated hypothyroidism
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083155	Immune-mediated arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083156	Immune-mediated dermatitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083347	Immune effector cell-associated neurotoxicity syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083406	Immune-mediated cholangitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083517	Immune-mediated hyperthyroidism

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLT, HLT, SOC, PT or L1T	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083521	Immune-mediated hepatic disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083522	Immune-mediated renal disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083636	Autoimmune cholangitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083812	Autoimmune heparin-induced thrombocytopenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083842	Immune thrombocytopenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083913	Acquired ATTR amyloidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10083961	Autoimmune blistering disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084153	Axonal and demyelinating polyneuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084237	Neonatal Crohn's disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084264	Optic perineuritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084296	Immune-mediated gastritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084305	Pleuroparenchymal fibroelastosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084306	Autoinflammation with infantile enterocolitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084550	Infected vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084701	Immune-mediated encephalopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084761	Reactive capillary endothelial proliferation
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084765	Immune-mediated cholestasis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084767	Multisystem inflammatory syndrome in children
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084828	Immune-mediated cytopenia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10084887	De novo purine synthesis inhibitors associated acute inflammatory syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085003	Sarcoid-like reaction
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085025	Immune-mediated hypophysitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085026	Immune-mediated oesophagitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085059	Retinal occlusive vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085069	Immune-mediated cystitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085070	Haemorrhagic occlusive retinal vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085188	Probable e-cigarette or vaping product use associated lung injury
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085189	Confirmed e-cigarette or vaping product use associated lung injury
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085219	Lupus anticoagulant hypoprothrombinaemia syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085324	Raynaud's phenomenon of the nipple
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085352	Immune-mediated lung disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085408	Food protein-induced enterocolitis syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085438	Anti-LRP2 nephropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085546	Immune-mediated neurological disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085547	Immune-mediated adrenal insufficiency
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085600	Acute aseptic arthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085657	Orofacial granulomatosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085753	Peripheral spondylarthrits
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085806	Myelin oligodendrocyte glycoprotein antibody-associated disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085850	Multisystem inflammatory syndrome in adults
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085884	Anogenital lichen planus
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085912	Anti-thyroid antibody increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10085970	Idiopathic inflammatory myopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086065	Rheumatoid meningitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086091	Multisystem inflammatory syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086130	Acute necrotising myelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086154	Facial myokymia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086157	Anti-platelet factor 4 antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086158	Thrombosis with thrombocytopenia syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086182	Complement fragment Bb increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086187	Undifferentiated spondylarthrits
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086201	Chronic inflammatory response syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086251	Fungal myositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086255	Diffuse infiltrative lymphocytosis syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086279	Rheumatoid bursitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086303	Food protein-induced enteropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086403	Hypergammaglobulinaemic purpura of Waldenström
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086436	Anaemic retinopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086444	Acute macular neuroretinopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086562	ASIA syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086663	Sarcoidosis of lymph node
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086722	Rheumatoid pleuritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086970	Anti-liver cytosol antibody type 1 positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10086982	Ischaemic demyelination
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087064	Mucous membrane pemphigoid
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087111	Useless hand syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087281	Immune-mediated scleritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087480	Immune-mediated myasthenia gravis

Table 12 List of MedDRA codes of ADRs related to the safety specification

Survey items	Special Interest AE Group	MedDRA Version	SMQ, HLG, HLT, SOC, PT or L1, L2	Code	Term (Japanese)
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087567	Immune-mediated pericarditis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087667	Anti-sulfatide autoantibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087719	Food protein-induced allergic proctocolitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087798	Ascending flaccid paralysis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087869	Polyradiculoneuropathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087875	Autoimmune cerebellar ataxia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087909	Gluten ataxia
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087914	Paradoxical skin reaction
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10087934	Lichen planus pemphigoides
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088058	Anti IFN gamma autoantibody syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088109	S100 protein increased
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088362	Immune-mediated optic neuritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088388	Antibody-dependent enhancement
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088389	Enhanced respiratory disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088550	Immune-mediated polyserositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088782	Incomplete thymus involution
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088816	CANOMAD syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088960	Immune-mediated myelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10088970	Adenosine deaminase 2 deficiency
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10089050	Rhupus syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10089169	Immune-mediated vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10089253	Scleroderma overlap syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10089280	Chronic sclerosing sialadenitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10089346	Immune-complex membranoproliferative glomerulonephritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10089622	Immune effector cell-associated HLH-like syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10089649	Pseudothetosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090022	Autoimmune hypoparathyroidism
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090023	Autoimmune ophoritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090172	Anogenital granulomatosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090212	Autoimmune nodopathy
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090214	Immune effector cell-associated haematotoxicity
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090251	Autoimmune myelitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090395	Immune-mediated gastrointestinal disorder
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090621	Generalised pustular psoriasis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090724	Myocarditis-myositis-myasthenia gravis overlap syndrome
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090740	Splenic sarcoidosis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090809	Autoimmune vasculitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090927	Adrenal antibody test positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090972	Immune-mediated mucositis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10090982	Immune-mediated proctitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091321	Tumour inflammation-associated neurotoxicity
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091343	Anti-nucleosome antibody positive
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091463	Seronegative spondylarthritis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091532	Childhood interstitial lung disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091577	Albuminocytological dissociation present
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091652	Ulcerative jejunitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091807	Enteropathic uveitis
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091840	Connective tissue disease-associated interstitial lung disease
Safety specification	Potential immune-mediated disease (pIMD)	28.0	PT	10091984	Presymptomatic type 1 diabetes mellitus

Table 13-1 Incidence of ADRs by safety specification (shock, anaphylaxis)

As of Sep 8, 2025

Subjects included in safety analysis

	Total		Serious	
Sample size	7707			
Number of subjects with ADRs	55		0	
Incidence proportion of ADRs (%)	0.7		0.0	
Type of ADR	Number of subjects with ADRs (%)			
Skin and subcutaneous tissue disorders	48	(0.6)	0	(0.0)
Rash	21	(0.3)	0	(0.0)
Urticaria	15	(0.2)	0	(0.0)
Eczema	9	(0.1)	0	(0.0)
Perioral dermatitis	2	(0.0)	0	(0.0)
Rash erythematous	2	(0.0)	0	(0.0)
Dermatitis contact	1	(0.0)	0	(0.0)
Rash pruritic	1	(0.0)	0	(0.0)
Circumoral swelling	1	(0.0)	0	(0.0)
General disorders and administration site conditions	6	(0.1)	0	(0.0)
Swelling face	2	(0.0)	0	(0.0)
Vaccination site eczema	2	(0.0)	0	(0.0)
Vaccination site rash	1	(0.0)	0	(0.0)
Vaccination site vesicles	1	(0.0)	0	(0.0)
Gastrointestinal disorders	3	(0.0)	0	(0.0)
Gingival swelling	2	(0.0)	0	(0.0)
Lip swelling	1	(0.0)	0	(0.0)
Eye disorders	2	(0.0)	0	(0.0)
Periorbital swelling	2	(0.0)	0	(0.0)
Swelling of eyelid	1	(0.0)	0	(0.0)

MedDRA/J (28.0)

Table 13-2 Outcome of ADRs by safety specification (shock, anaphylaxis)

As of Sep 8, 2025

Subjects included in safety analysis

	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707						7707					
Number of subjects with ADRs (by seriousness)	0						55					
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	8	46	1
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)
Gastrointestinal disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Gingival swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Lip swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (0.1)	40 (0.5)	1 (0.0)
Dermatitis contact	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.1)	0 (0.0)
Perioral dermatitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	19 (0.2)	0 (0.0)
Rash erythematous	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Rash pruritic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urticaria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	9 (0.1)	1 (0.0)
Circumoral swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
General disorders and administration site conditions	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Swelling face	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Vaccination site rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site vesicles	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vaccination site eczema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)

MedDRA/J (28.0)

If multiple events with the same PT occur in the same subject, the events will be tabulated based on the following priority: (1) Serious > Non-serious, and (2) Death > Recovered with sequelae > Not recovered > Recovering > Recovered > Unknown.

Table13-3 List of subjects of ADRs related to safety specification (shock, anaphylaxis)

As of Sep 8, 2025

Subjects included in safety analysis

Case Number	Name of event (MedDRA_PT)	Severity (grade)	Seriousness	Period from the date of first vaccination to the date of ADRs onset [days]	Period from the date of the second vaccination to the date of ADRs onset [days]	Outcomes	Gender	Age	Medical history	Underlying diseases
PPD	Rash	1	Non-serious	1	-	Resolved	PPD		No	Yes
	Rash	Unknown	Non-serious	1	-	Resolved			No	Yes
	Rash	1	Non-serious	2	-	Resolved			Yes	No
	Vaccination site rash	1	Non-serious	2	-	Resolved			No	No
	Gingival swelling	1	Non-serious	3	-	Resolved			No	Yes
	Vaccination site vesicles	1	Non-serious	-	3	Resolved			No	Yes
	Vaccination site eczema	2	Non-serious	1	-	Resolved			No	Yes
	Eczema	2	Non-serious	1	-	Resolved			No	Yes
	Rash	1	Non-serious	-	2	Resolved			No	Yes
	Urticaria	Unknown	Non-serious	4	-	Unknown			No	No
	Circumoral swelling	1	Non-serious	2	-	Resolved			Yes	Yes
	Swelling face	1	Non-serious	2	-	Resolved			Yes	Yes
	Rash	1	Non-serious	5	-	Resolved			Yes	Yes
	Rash erythematous	1	Non-serious	5	-	Resolved			Yes	Yes
	Urticaria	1	Non-serious	3	-	Resolving			No	Yes
	Rash	1	Non-serious	2	-	Resolved			No	Yes
	Rash	Unknown	Non-serious	2	-	Resolved			No	Yes
	Lip swelling	1	Non-serious	2	-	Resolved			Yes	Yes
	Lip swelling	1	Non-serious	-	2	Resolved			Yes	Yes
	Urticaria	2	Non-serious	-	4	Resolving			No	No
	Rash	1	Non-serious	3	-	Resolved			No	No
	Rash	2	Non-serious	1	-	Resolving			No	Yes
	Eczema	1	Non-serious	22	-	Resolved			No	Yes
	Eczema	1	Non-serious	2	-	Resolved			No	No
	Eczema	1	Non-serious	-	2	Resolved			No	No
	Eczema	1	Non-serious	7	-	Resolved			No	No
	Vaccination site eczema	1	Non-serious	-	4	Resolved			No	No
	Urticaria	1	Non-serious	1	-	Resolved			No	No
	Rash	2	Non-serious	1	-	Resolved			No	Yes
	Urticaria	1	Non-serious	2	-	Resolving			No	Yes
	Eczema	1	Non-serious	1	-	Resolved			No	Yes
	Eczema	1	Non-serious	4	-	Resolved			No	Yes
	Rash	1	Non-serious	3	-	Resolving			No	Yes
	Rash	1	Non-serious	4	-	Resolved			No	Yes
	Urticaria	1	Non-serious	2	-	Resolved			No	Yes
	Rash	1	Non-serious	2	-	Resolved			No	No
	Rash erythematous	1	Non-serious	2	-	Resolved			No	Yes
	Rash erythematous	1	Non-serious	11	-	Resolved			No	Yes
	Rash	2	Non-serious	1	-	Resolved			No	Yes
	Periorbital swelling	1	Non-serious	1	-	Resolved			No	Yes
	Swelling face	1	Non-serious	1	-	Resolved			No	Yes
	Gingival swelling	1	Non-serious	1	-	Resolved			No	Yes
	Urticaria	1	Non-serious	-	1	Resolved			No	No
	Rash	1	Non-serious	3	-	Resolved			Yes	No
	Eczema	1	Non-serious	1	-	Resolved			No	Yes
	Urticaria	1	Non-serious	11	-	Resolving			No	No
	Swelling of eyelid	3	Non-serious	-	18	Resolving			No	No
	Periorbital swelling	3	Non-serious	-	18	Resolving			No	No
	Eczema	1	Non-serious	1	-	Resolved			No	No
	Urticaria	1	Non-serious	4	-	Resolving			No	No
	Urticaria	1	Non-serious	-	2	Resolving			No	No
	Urticaria	2	Non-serious	1	-	Resolved			No	No
	Rash	1	Non-serious	2	-	Resolved			No	Yes
	Rash	1	Non-serious	-	4	Resolved			No	Yes
	Rash	1	Non-serious	2	-	Resolved			No	Yes
	Rash pruritic	1	Non-serious	-	2	Resolved			No	Yes
	Rash	1	Non-serious	6	-	Resolved			No	No
	Rash	1	Non-serious	3	-	Resolved			No	No
	Dermatitis contact	1	Non-serious	-	2	Resolved			No	No
	Urticaria	1	Non-serious	-	4	Resolved			No	No
	Dermatitis contact	1	Non-serious	-	6	Resolved			No	No
	Perioral dermatitis	1	Non-serious	-	1	Resolved			No	Yes
	Perioral dermatitis	2	Non-serious	-	-	Resolved			Yes	No
	Urticaria	1	Non-serious	17	-	Resolved			No	No
	Rash	1	Non-serious	2	-	Resolved			No	No
	Urticaria	1	Non-serious	11	-	Resolved			No	Yes
	Urticaria	1	Non-serious	9	-	Resolved			No	Yes
	Urticaria	1	Non-serious	-	2	Resolved			No	Yes
	Eczema	1	Non-serious	-	3	Resolved			No	No

Table 14-1 Incidence of ADRs by safety specification (diseases suspected to be immune-mediated)

As of Sep 8, 2025

Subjects included in safety analysis

	Total	Serious
Sample size	7707	
Number of subjects with ADRs	2	1
Incidence proportion of ADRs (%)	0.0	0.0
Type of ADR	Number of subjects with ADRs (%)	
Skin and subcutaneous tissue disorders	1 (0.0)	0 (0.0)
Butterfly rash	1 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	1 (0.0)	1 (0.0)
Rheumatoid arthritis	1 (0.0)	1 (0.0)

MedDRA/J (28.0)

Table 14-2 Outcome of ADRs by safety specification (diseases suspected to be immune-mediated)

As of Sep 8, 2025

Subjects included in safety analysis

	Serious						Non-serious					
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Sample size	7707						7707					
Number of subjects with ADRs (by seriousness)	1						1					
Number of subjects with ADRs	0	0	0	1	0	0	0	0	0	0	1	0
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)					
Skin and subcutaneous tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Butterfly rash	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rheumatoid arthritis	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA/J (28.0)

If multiple events with the same PT occur in the same subject, the events will be tabulated based on the following priority: (1) Serious > Non-serious, and (2) Death > Recovered with sequelae > Not recovered > Recovering > Recovered > Unknown.

Table 15 Listing of incidence of ADRs by subjects

As of Sep 8, 2025

Subjects included in safety analysis

Characteristics of subjects inoculated		Number of subjects surveyed	Solicited adverse events		Unsolicited adverse events		Combined total	
			Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)	Number of subjects with ADRs	Incidence proportion of ADRs (%)
Total		7707	6394	83.0	754	9.8	6406	83.1
Sex	Male	2495	1984	79.5	130	5.2	1988	79.7
	Female	5212	4410	84.6	624	12.0	4418	84.8
Pregnancy (females only)	No	5212	4410	84.6	624	12.0	4418	84.8
	Yes	0	0	—	0	—	0	—
Age 1 [years] Mean±SD: 66.0±10.3 Maximum: 102 Median: 66.0 Minimum: 19	≤15	0	0	—	0	—	0	—
	15≤ to <50	91	78	85.7	13	14.3	78	85.7
	50≤ to <65	3406	2895	85.0	416	12.2	2899	85.1
	65≤ to <75	2524	2124	84.2	216	8.6	2128	84.3
	75≤	1686	1297	76.9	109	6.5	1301	77.2
	≥65	3497	2973	85.0	429	12.3	2977	85.1
Age 2 [years]	≤65	4210	3421	81.3	325	7.7	3429	81.4
	≥65	0	0	—	0	—	0	—
Age 3 [years]	≤18	7707	6394	83.0	754	9.8	6406	83.1
	≥18	7285	6031	82.8	683	9.4	6042	82.9
History of vaccination with herpes zoster vaccine other than Shingrix	No	115	96	83.5	13	11.3	96	83.5
	Yes	307	267	87.0	58	18.9	268	87.3
History of herpes zoster	Unknown	6221	5116	82.2	570	9.2	5125	82.4
	No	742	634	85.4	82	11.1	636	85.7
	Yes	744	644	86.6	102	13.7	645	86.7
	Unknown	768	6358	82.9	751	9.8	6370	83.1
Eligibility as subjects requiring precaution for vaccination	No	39	36	92.3	3	7.7	36	92.3
	Yes	7005	5758	82.2	639	9.1	5770	82.4
Immune abnormality	No	702	636	90.6	115	16.4	636	90.6
	Yes	7035	5786	82.2	641	9.1	5798	82.4
Underlying diseases related to immune abnormalities	No	672	608	90.5	113	16.8	608	90.5
	Yes	7072	5820	82.3	657	9.3	5832	82.5
Prior medications (drugs that may affect immunity)	No	635	574	90.4	97	15.3	574	90.4
	Yes	7699	6388	83.0	754	9.8	6400	83.1
Prior therapies (therapies that may affect immunity)	No	8	6	75.0	0	0.0	6	75.0
	Yes	3761	2930	77.9	250	6.6	2938	78.1
Underlying disease*	No	3946	3464	87.8	504	12.8	3468	87.9
	Yes	7597	6304	83.0	740	9.7	6315	83.1
Underlying disease (kidney disease)	No	110	90	81.8	14	12.7	91	82.7
	Yes	7541	6252	82.9	723	9.6	6264	83.1
Underlying disease (liver disease)	No	166	142	85.5	31	18.7	142	85.5
	Yes	3795	2958	77.9	255	6.7	2966	78.2
Underlying disease (other)	No	3912	3436	87.8	499	12.8	3440	87.9
	Yes	7073	5828	82.4	670	9.5	5839	82.6
Medical history	No	634	566	89.3	84	13.2	567	89.4
	Yes	7481	6189	82.7	726	9.7	6200	82.9
Vaccines administered for the initial vaccination other than Shingrix	No	226	205	90.7	28	12.4	206	91.2
	Yes	7275	6078	83.5	699	9.6	6088	83.7
Vaccines administered for the second vaccination other than Shingrix (only for subjects receiving the second vaccination)	No	189	161	85.2	26	13.8	162	85.7
	Yes	7635	6328	82.9	743	9.7	6340	83.0
Vaccines administered concomitantly with the initial vaccination	No	72	66	91.7	11	15.3	66	91.7
	Yes	7431	6210	83.6	720	9.7	6221	83.7
Vaccines administered concomitantly with the second vaccination (only for subjects receiving the second vaccination)	No	33	29	87.9	5	15.2	29	87.9
	Yes	4345	3381	77.8	259	6.0	3390	78.0
Medications used	No	3362	3013	89.6	495	14.7	3016	89.7
	Yes	7653	6349	83.0	748	9.8	6361	83.1
Non-drug therapies administered	No	54	45	83.3	6	11.1	45	83.3
	Yes	—	—	—	—	—	—	—

* "Underlying diseases" include underlying diseases related to immune abnormality, kidney diseases, liver diseases, and others

Note) If the date of ADR onset is unknown, data will be tabulated under the initial vaccination. If solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Table 16-1 Incidence of ADRs in subjects with special vaccine backgrounds (elderly)

Subjects included in safety analysis

As of Sep 8, 2025

Sample site	Solicited adverse events												Unsolicited adverse events												Unsolicited total															
	-65				65+				Total				-65				65+				Total				-65				65+				Total				Total			
	Total		Serious		Total		Serious		Total		Serious		Total		Serious		Total		Serious		Total		Serious		Total		Serious		Total		Serious		Total		Serious					
	2973	4497	0	0	3421	4210	0	0	6394	7707	0	0	429	3497	3	0	325	4210	2	0	754	7707	5	0	2977	4497	3	0	3429	4210	2	0	6406	7707	5	0	8317	8111	0	0
Incidence proportion of ADRs (%)	85.9	81.7	0.0	0.0	82.2	81.7	0.0	0.0	83.7	81.7	0.0	0.0	12.3	81.7	0.1	0.0	12.3	81.7	0.0	0.0	23.4	81.7	0.1	0.0	85.9	81.7	0.1	0.0	82.2	81.7	0.0	0.0	83.7	81.7	0.0	0.0	85.9	81.7	0.0	0.0
Type of ADR	Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)			
General disorders and administration site conditions	2998	484.6	0	0.0%	3404	480.9	0	0.0%	6302	482.5	0	0.0%	211	6.0	0	0.0%	153	1.6	0	0.0%	364	4.7	0	0.0%	2958	484.6	0	0.0%	3407	480.9	0	0.0%	6305	482.6	0	0.0%	3225	478.5	0	0.0%
Vaccination site pain	2642	481.3	0	0.0%	3125	476.4	0	0.0%	5667	478.7	0	0.0%	8	0.2	0	0.0%	8	0.2	0	0.0%	16	0.2	0	0.0%	2642	481.3	0	0.0%	3125	476.4	0	0.0%	5668	478.7	0	0.0%	3226	478.6	0	0.0%
Vaccination site swelling	1924	455.0	0	0.0%	2264	453.8	0	0.0%	4188	454.3	0	0.0%	7	0.2	0	0.0%	4	0.1	0	0.0%	11	0.2	0	0.0%	1925	455.0	0	0.0%	2266	453.8	0	0.0%	4191	454.4	0	0.0%	3227	478.7	0	0.0%
Vaccination site erythema	1842	452.7	0	0.0%	2225	452.9	0	0.0%	4067	452.8	0	0.0%	8	0.2	0	0.0%	5	0.1	0	0.0%	13	0.2	0	0.0%	1844	452.7	0	0.0%	2226	452.9	0	0.0%	4070	452.8	0	0.0%	3228	478.8	0	0.0%
Fatigue	1721	449.2	0	0.0%	1428	433.9	0	0.0%	3149	440.9	0	0.0%	8	0.2	0	0.0%	6	0.1	0	0.0%	14	0.2	0	0.0%	1723	449.3	0	0.0%	1431	434.0	0	0.0%	3154	440.9	0	0.0%	3229	478.9	0	0.0%
Pyrexia	1742	449.8	0	0.0%	1355	432.3	0	0.0%	3097	440.2	0	0.0%	6	0.2	0	0.0%	2	0.0	0	0.0%	8	0.1	0	0.0%	1746	449.9	0	0.0%	1355	432.3	0	0.0%	3101	440.2	0	0.0%	3230	479.0	0	0.0%
Chills	908	28.0	0	0.0%	40	11.6	0	0.0%	1308	18.3	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	6	0.1	0	0.0%	909	28.0	0	0.0%	40	11.7	0	0.0%	1400	18.3	0	0.0%	3231	479.1	0	0.0%
Vaccination site pruritus	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	128	3.7	0	0.0%	94	2.2	0	0.0%	222	2.9	0	0.0%	0	0.0	0	0.0%	94	2.2	0	0.0%	222	2.9	0	0.0%	3232	479.2	0	0.0%
Malaise	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	22	0.6	0	0.0%	22	0.5	0	0.0%	44	0.6	0	0.0%	0	0.0	0	0.0%	22	0.5	0	0.0%	44	0.6	0	0.0%	3233	479.3	0	0.0%
Chest pain	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	5	0.1	0	0.0%	8	0.2	0	0.0%	13	0.2	0	0.0%	5	0.1	0	0.0%	8	0.2	0	0.0%	13	0.2	0	0.0%	3234	479.4	0	0.0%
Pain	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	9	0.3	0	0.0%	3	0.1	0	0.0%	12	0.2	0	0.0%	9	0.3	0	0.0%	3	0.1	0	0.0%	12	0.2	0	0.0%	3235	479.5	0	0.0%
Vaccination site warmth	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	6	0.2	0	0.0%	6	0.1	0	0.0%	12	0.2	0	0.0%	6	0.2	0	0.0%	6	0.1	0	0.0%	12	0.2	0	0.0%	3236	479.6	0	0.0%
Axillary pain	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	11	0.3	0	0.0%	0	0.0	0	0.0%	11	0.1	0	0.0%	11	0.3	0	0.0%	0	0.0	0	0.0%	11	0.1	0	0.0%	3237	479.7	0	0.0%
Feeling abnormal	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	5	0.1	0	0.0%	2	0.0	0	0.0%	7	0.1	0	0.0%	5	0.1	0	0.0%	2	0.0	0	0.0%	7	0.1	0	0.0%	3238	479.8	0	0.0%
Swelling	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	5	0.1	0	0.0%	2	0.0	0	0.0%	7	0.1	0	0.0%	5	0.1	0	0.0%	2	0.0	0	0.0%	7	0.1	0	0.0%	3239	479.9	0	0.0%
Thirst	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	4	0.1	0	0.0%	2	0.0	0	0.0%	6	0.1	0	0.0%	4	0.1	0	0.0%	2	0.0	0	0.0%	6	0.1	0	0.0%	3240	480.0	0	0.0%
Asthenia	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	5	0.1	0	0.0%	0	0.0	0	0.0%	5	0.1	0	0.0%	5	0.1	0	0.0%	0	0.0	0	0.0%	5	0.1	0	0.0%	3241	480.1	0	0.0%
Feeling hot	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	3	0.1	0	0.0%	2	0.0	0	0.0%	5	0.1	0	0.0%	3	0.1	0	0.0%	2	0.0	0	0.0%	5	0.1	0	0.0%	3242	480.2	0	0.0%
Peripheral swelling	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	3	0.1	0	0.0%	1	0.0	0	0.0%	4	0.1	0	0.0%	3	0.1	0	0.0%	1	0.0	0	0.0%	4	0.1	0	0.0%	3243	480.3	0	0.0%
Oedema peripheral	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	3	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	3	0.0	0	0.0%	3244	480.4	0	0.0%
Vaccination site induration	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	3	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	3	0.0	0	0.0%	3245	480.5	0	0.0%
Vaccination site discoloration	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	3	0.1	0	0.0%	0	0.0	0	0.0%	3	0.0	0	0.0%	3	0.1	0	0.0%	0	0.0	0	0.0%	3	0.0	0	0.0%	3246	480.6	0	0.0%
Confluent aggravated	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	2	0.0	0	0.0%	2	0.0	0	0.0%	0	0.0	0	0.0%	2	0.0	0	0.0%	2	0.0	0	0.0%	3247	480.7	0	0.0%
Feeling cold	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	3248	480.8	0	0.0%
Swelling face	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	2	0.0	0	0.0%	2	0.0	0	0.0%	0	0.0	0	0.0%	2	0.0	0	0.0%	2	0.0	0	0.0%	3249	480.9	0	0.0%
Vaccination site burning	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	3250	481.0	0	0.0%
Vaccination site eczema	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	2	0.0	0	0.0%	3251	481.1	0	0.0%
Discomfort	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	3252	481.2	0	0.0%
Facial pain	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	3253	481.3	0	0.0%
Injection site paresthesia	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	3254	481.4	0	0.0%
Muscle	0	0.0	0	0.0%	0	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	1	0.0	0	0.0%	0	0.0	0	0.0%	1	0.0	0	0.0%	3255			

As of Sep 8, 2025

As of Sep 8, 2025

150/196

Table 16-1 Incidence of ADRs in subjects with special vaccinee backgrounds (elderly)

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Safety											
	Solicited adverse events						Unsolicited adverse events					
	-65		65+		Total		-65		65+		Total	
	Total	Serious	Total	Serious	Total	Serious	Total	Serious	Total	Serious	Total	Serious
Number of subjects with ADRs	2973	0	6421	0	6394	0	429	3	825	2	754	5
Incidence proportion of ADRs (%)	85.7	0.0	84.1	0.0	83.7	0.0	12.3	0.1	27.7	0.0	24.7	0.1
Type of ADR	Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
Ear and labyrinth disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (0.3)	0 (0.0)	3 (0.1)	0 (0.0)	15 (0.2)	0 (0.0)
Tinnitus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	1 (0.0)	0 (0.0)	6 (0.1)	0 (0.0)
Ear pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Ear discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.1)	0 (0.0)
Hypoaacusis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Ear pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Eye disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.3)	0 (0.0)	3 (0.1)	1 (0.0)	14 (0.2)	1 (0.0)
Eye pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)
Eye discharge	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Eye pruritus	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Periorbital swelling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Eye inflammation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Eye irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Retinal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling of eyelid	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Vision blurred	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Visual acuity reduced	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
eyelid irritation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
eyelid pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (0.3)	1 (0.0)	3 (0.1)	0 (0.0)	14 (0.2)	1 (0.0)
Peripheral edema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	0 (0.0)	5 (0.1)	0 (0.0)	0 (0.0)
Hot flush	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Flushing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Internal haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Infectious and infestations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.3)	0 (0.0)	3 (0.1)	0 (0.0)	13 (0.2)	0 (0.0)
Oral herpes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	2 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)
Rhinitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Gastroenteritis viral	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Herpes virus infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pustule	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Cystitis bacterial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Candida disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.2)	0 (0.0)	6 (0.1)	0 (0.0)	12 (0.2)	0 (0.0)
Palpitations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.2)	0 (0.0)	6 (0.1)	0 (0.0)	12 (0.2)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Polakiuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)
Nocturia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Haematuria	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Polynia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Urethral pain	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Investigations	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.1)	0 (0.0)	4 (0.1)	0 (0.0)	7 (0.1)	0 (0.0)
Blood pressure increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
Heart rate increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)
C-reactive protein increased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Heart rate	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Oxygen saturation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Psychiatric disorders	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.1)	1 (0.0)	4 (0.1)	1 (0.0)	7 (0.1)	1 (0.0)
Dissociative disorder	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Euphoric mood	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Hallucination	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	3 (0.0)	1 (0.0)
Lactose	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	2 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)
Heat illness	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

MedDRA/J (28.0)

Subjects included in safety analysis

[illegible]

Subjects included in safety analysis

Sample size		Elderly												Total											
		Selected adverse events						Total						Selected adverse events						Total					
		Deaths		Recovered with sequelae		Not recovered		Deaths		Recovered with sequelae		Not recovered		Deaths		Recovered with sequelae		Not recovered		Deaths		Recovered with sequelae		Not recovered	
U		U		U		U		U		U		U		U		U		U		U		U		U	
Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)		Number of subjects with ADRs (%)	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U		U		U	
U		U		U		U		U		U		U		U		U		U		U					

Table 16-2 Outcome of ADRs in subjects with special vaccinee backgrounds (elderly)

Subjects included in safety analysis

Sample size	Elderly																			
	Solicited adverse events										Total									
	Death					Recovered with sequelae					Not recovered					Recovering				
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Number of subjects with ADRs	0	0	0	0	0	208	226	274	0	0	0	0	0	0	0	0	0	0	0	0
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)									
Respiratory system disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hemoptysis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nosebleed	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary embolism	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumothorax	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dyspnea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoxemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Wheezing	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vocal fremitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
General disorders and administration site conditions	0	(0.0)	0	(0.0)	0	(0.0)	208	(5.9)	2750	(78.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Aches	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chills	0	(0.0)	0	(0.0)	0	(0.0)	29	(0.8)	879	(25.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	78	(2.2)	1642	(47.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	135	(1.8)
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	0	(0.0)	0	(0.0)	0	(0.0)	75	(2.1)	1667	(47.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	122	(1.6)
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Achy pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Reduced limb mobility	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site erythema	0	(0.0)	0	(0.0)	0	(0.0)	92	(2.7)	1749	(50.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	208	(2.7)
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site pain	0	(0.0)	0	(0.0)	0	(0.0)	132	(3.8)	2710	(77.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	299	(3.7)
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site numb	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site swelling	0	(0.0)	0	(0.0)	0	(0.0)	92	(2.7)	1829	(52.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	201	(2.6)
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertension and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

If multiple events with the same PT occur in the same subject, the events will be tabulated based on the following priority: (1) Serious > Non-serious, and (2) Death > Recovered with sequelae > Not recovered > Recovering > Unknown.
Note) If the onset date of an ADR was unknown and solicited/unolicited status could not be determined, the ADR was counted only in the combined total.

Table 16-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Elderly												Total											
	Unidentified adverse events												Unidentified adverse events											
	75												75											
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown
Number of subjects with ADRs	0	0	0	1	30	397	0	0	0	4	21	304	0	0	0	7	31	301	0	0	0	31	301	0
Type of ADR	Number of subjects with ADRs (%)												Number of subjects with ADRs (%)											
Infections and infestations	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)
Conjunctivitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Gastroenteritis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Gastroenteritis viral	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Herpes virus infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Herpes zoster	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Papule	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Rhinitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Cystitis bacterial	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Blood and lymphatic system disorders	0	(0.0)	0	(0.0)	0	(0.0)	16	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Lymph node pain	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphadenopathy	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	15	(0.2)
Metabolism and nutrition disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	8	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	15	(0.4)	0	(0.0)	2	(0.0)
Decreased appetite	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	15	(0.4)	0	(0.0)	2	(0.0)
Psychiatric disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dissociative disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Euphoric mood	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Hallucination	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Lethargy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Nervous system disorders	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	53	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.1)
Dizziness	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	27	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	10	(0.3)	0	(0.0)	2	(0.0)
Dizziness postural	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Dyspareunia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Head discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Headache	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)
Hypoesthesia	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	10	(0.1)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Movement disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Neuralgia	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	1	(0.0)	0	(0.0)	9	(0.1)
Paresthesia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Peripheral nerve palsy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Somnolence	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	10	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.2)	0	(0.0)	0	(0.0)	18	(0.2)
Tremor	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Balance disorder	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)	5	(0.1)
Taste disorder	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Brain fog	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Eye disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	10	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	13	(0.2)
Eye discharge	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Eye inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye pain	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Retinal hemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Swelling of eyelid	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vision blurred	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Visual acuity reduced	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye pruritus	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Periorbital swelling	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye/eyelid irritation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye/eyelid pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Ear and labyrinth disorders	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Ear pain	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)
Hypacusis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Ear discomfort	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Eur tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Otitis disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	7	(0.1)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	7	(0.1)

Table 16-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Elderly															
	Unidentified adverse events															
	25															
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering
Number of subjects with ADRs	0	0	0	1	30	397	0	0	0	1	21	304	0	0	0	31
Type of ADR	Number of subjects with ADRs (%)															
Constitutional disorders	0	(0.0)	0	(0.0)	0	(0.0)	40	(1.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain upper	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cheilitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gingival pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Melasma	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Salivary gland pain	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Stomatitis	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue rough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Toothache	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vomiting	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lip blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoesthesia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Parosmia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue exfoliation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosa erosion	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Loose tooth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Facies soft	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Anal incontinence	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosal roughening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.3)	7	(0.2)	1	(0.0)	66	(1.8)	0	(0.0)
Blister	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Dermatitis contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Erythema	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Pain of skin	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Perioral dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	0	(0.0)	0	(0.0)	6	(1.2)	53	(1.5)	0	(0.0)	0	(0.0)	4	(0.1)	43	(1.0)
Purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Rash	0	(0.0)	0	(0.0)	2	(0.1)	5	(0.1)	0	(0.0)	0	(0.0)	14	(0.3)	0	(0.0)
Rash erythematous	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Rash pruritic	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Scall	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin discolouration	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	0	(0.0)	0	(0.0)	3	(0.1)	7	(0.2)	1	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Skin tightness	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin induration	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin burning sensation	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Butterfly rash	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Circumoral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.3)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)
Arthralgia	0	(0.0)	0	(0.0)	2	(0.1)	57	(1.6)	0	(0.0)	0	(0.0)	27	(0.8)	0	(0.0)
Back pain	0	(0.0)	0	(0.0)	0	(0.0)	22	(0.6)	0	(0.0)	0	(0.0)	10	(0.3)	0	(0.0)
Bone pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Flank pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Groin pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Muscle weakness	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	1	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Myalgia	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	1	(0.0)	6	(0.2)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)
Pain in extremity	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.3)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Muscle tightness	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	2	(0.1)	7	(0.2)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)

Table 16-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Elderly																			
	Unidentified adverse events																			
	255										255									
	Death					Recovered with sequelae					Not recovered					Recovering				
Number of subjects with ADRs	0	0	0	1	30	397	2	0	0	0	0	0	0	0	0	0	0	0	0	0
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)									
Respiratory disorders	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Haematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nocturia	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Polakiuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Poluria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
General disorders and administration site conditions	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.2)	203	(5.6)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Aches	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	3	(0.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chills	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injection site paronychia	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	21	(0.6)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Mus	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritis	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	19	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Periphereal swelling	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site erythema	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site pain	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	126	(3.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site swelling	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

If multiple events with the same PT occur in the same sub
 Note) If the onset date of an ADR was unknown and odds

Table 16-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Elderly																			
	Confirmed total																			
	75										75									
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae
Number of subjects with ADRs	0	0	0	240	2737	0	0	0	4210	246	3182	1	0	0	7787	466	3919	1	0	
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)									
Infections and infestations	0	(0.0)	0	(0.0)	0	(0.1)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)
Conjunctivitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Gastroenteritis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Gastroenteritis viral	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Herpes virus infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Herpes zoster	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Papule	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Rhinitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Cystitis bacterial	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Blood and lymphatic system disorders	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	20	(0.3)
Lymph node pain	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphadenopathy	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	15	(0.2)
Metabolism and nutrition disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	24	(0.3)
Decreased appetite	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	24	(0.3)
Psychiatric disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Dissociative disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Euphoric mood	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Hallucination	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Losses	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Nervous system disorders	0	(0.0)	0	(0.0)	0	(0.0)	67	(1.9)	1429	(40.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	124	(1.4)
Dizziness	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	227	(6.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)
Dizziness postural	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	3	(0.0)
Dyspareunia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysgeusia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Head discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.0)
Headache	0	(0.0)	0	(0.0)	0	(0.0)	65	(1.9)	1422	(40.7)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	118	(1.2)
Hypoesthesia	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Movement disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Neuralgia	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	5	(0.1)	1	(0.0)	0	(0.0)	9	(0.1)
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Peripheral nerve palsy	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Somnolence	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	18	(0.2)
Tremor	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Balance disorder	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)	3	(0.1)	0	(0.0)	2	(0.0)
Taste disorder	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Brain fog	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Eye disorders	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	(0.2)
Eye discharge	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Eye inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye pain	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Retinal hemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Swelling of eyelid	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vision blurred	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Visual acuity reduced	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye pruritus	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Periorbital swelling	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye redness	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Ear and labyrinth disorders	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)
Ear pain	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)
Hypacusis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Ear discomfort	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Ear ringing	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Otitis disorders	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.0)
Clinical disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)
Vascular disorders	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.3)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	13	(0.2)
Fainting	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Hypertension	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Hypertension	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Peripheral coldness	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)
Hot flush	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Internal hemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Respiratory, thoracic and mediastinal disorders	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	22	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Cough	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)
Dyspnea	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Epistaxis	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Nasal congestion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Nasal congestion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Productive cough	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)	0</									

As of Sep 8, 2025

As of Sep 8, 2025

Sample size	AD																								Elderly Age								Total																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
	Death								Recovered with sequelae								Not recovered								Death								Recovered with sequelae								Not recovered																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
	U								U								U								U								U								U								U																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
	N=1597								N=4210								N=3662								N=1787								N=366								N=9019																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
Number of subjects with ADHR (%)																								Number of subjects with ADHR (%)																								Number of subjects with ADHR (%)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
Type of ADR	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(

Table 16-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Elderly																			
	Confirmed total										Total									
	785					785					785					785				
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Death	Recovered with sequelae	Not recovered	Recovering	Recovered
Number of subjects with ADRs	0	0	0	1	240	0	0	0	0	246	0	0	0	466	5919	0	0	0	0	0
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)									
Head and sensory disorders	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.2)	0	(0.0)	0	(0.0)
Hemianopia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Nocutanea	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Polakiuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)
Polyuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
General disorders and administration site conditions	0	(0.0)	0	(0.0)	0	(0.0)	210	(6.0)	2748	(78.6)	0	(0.0)	0	(0.0)	0	(0.0)	223	(6.3)	3185	(78.6)
Aches	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	3	(0.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chills	0	(0.0)	0	(0.0)	0	(0.0)	29	(0.8)	880	(22.2)	0	(0.0)	0	(0.0)	0	(0.0)	15	(0.3)	477	(11.3)
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	78	(2.2)	1644	(47.0)	1	(0.0)	0	(0.0)	0	(0.0)	57	(1.4)	1373	(32.6)
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Injection site paronychia	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	21	(0.6)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	19	(0.5)
Muscle	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	8	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)
Prycia	0	(0.0)	0	(0.0)	0	(0.0)	75	(2.1)	1671	(47.8)	0	(0.0)	0	(0.0)	0	(0.0)	47	(1.1)	1307	(31.0)
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	19	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Femoral pain	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site erythema	0	(0.0)	0	(0.0)	0	(0.0)	92	(2.7)	1751	(50.1)	0	(0.0)	0	(0.0)	115	(2.7)	2110	(50.1)	1	(0.0)
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Vaccination site pain	0	(0.0)	0	(0.0)	0	(0.0)	132	(3.8)	2710	(77.5)	0	(0.0)	0	(0.0)	157	(3.7)	3070	(77.5)	1	(0.0)
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	126	(3.6)	0	(0.0)	0	(0.0)	3	(0.1)	91	(2.2)	0	(0.0)
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site haematoma	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site swelling	0	(0.0)	0	(0.0)	0	(0.0)	95	(2.7)	1930	(52.3)	0	(0.0)	0	(0.0)	106	(2.5)	2159	(51.3)	1	(0.0)
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	4	(0.1)	0	(0.0)
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heavy, posturing and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)

If multiple events with the same PT occur in the same sub
Note) If the onset date of an ADR was unknown and odds

MedDRA v 28.0y

Table 17-1 Incidence of ADRs in subjects with special vaccinee backgrounds (renal impairment)

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Solicited adverse events																		Unsolicited adverse events																		Unsolicited total																	
	Yes				No				Total				Yes				No				Total				Yes				No				Total																					
	Total		1/0		0		0		Total		1/0		0		0		Total		1/0		0		0		Total		1/0		0		0																							
	Total	1/0	0	0	Total	1/0	0	0	Total	1/0	0	0	Total	1/0	0	0	Total	1/0	0	0	Total	1/0	0	0	Total	1/0	0	0	Total	1/0	0	0																						
Number of subjects with ADRs	90	81.1	0	0	6394	6317	0	0	14	12.7	0	0	740	637	3	0	754	754	0	0	90	81.1	0	0	6315	6317	0	0	6406	6317	0	0																						
Incidence proportion of ADRs (%)	81.1	0.0	0.0	0.0	83.7	0.0	0.0	0.0	12.7	0.0	0.0	0.0	10.1	0.0	0.1	0.0	10.1	0.0	0.1	0.0	81.1	0.0	0.0	0.0	81.1	0.0	0.0	0.0	83.7	0.0	0.0	0.0																						
Type of ADR	Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)				Number of subjects with ADRs (%)																					
General disorders and administration site conditions	90 (81.8)	0	0 (0.0)	0 (0.0)	6272 (82.6)	0	0 (0.0)	0 (0.0)	8 (0.0)	8 (7.3)	0	0 (0.0)	356 (4.7)	0	0 (0.0)	364 (4.7)	0	0 (0.0)	90 (81.8)	0	0 (0.0)	0 (0.0)	6275 (82.6)	0	0 (0.0)	0 (0.0)	6365 (82.6)	0	0 (0.0)	0 (0.0)	6365 (82.6)	0	0 (0.0)																					
Vaccination site pain	83 (75.5)	0	0 (0.0)	0 (0.0)	5964 (78.8)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	16 (0.2)	0	0 (0.0)	16 (0.2)	0	0 (0.0)	83 (75.5)	0	0 (0.0)	0 (0.0)	5967 (78.8)	0	0 (0.0)	0 (0.0)	6070 (78.8)	0	0 (0.0)	0 (0.0)	6070 (78.8)	0	0 (0.0)																					
Vaccination site swelling	49 (44.5)	0	0 (0.0)	0 (0.0)	4139 (54.5)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	11 (0.1)	0	0 (0.0)	11 (0.1)	0	0 (0.0)	49 (44.5)	0	0 (0.0)	0 (0.0)	4142 (54.5)	0	0 (0.0)	0 (0.0)	4191 (54.4)	0	0 (0.0)	0	0 (0.0)	4191 (54.4)	0	0 (0.0)																				
Vaccination site erythema	47 (42.7)	0	0 (0.0)	0 (0.0)	4020 (52.9)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	13 (0.2)	0	0 (0.0)	13 (0.2)	0	0 (0.0)	47 (42.7)	0	0 (0.0)	0 (0.0)	4023 (53.0)	0	0 (0.0)	0 (0.0)	4070 (52.8)	0	0 (0.0)	0	0 (0.0)	4070 (52.8)	0	0 (0.0)																				
Fatigue	43 (39.1)	0	0 (0.0)	0 (0.0)	3106 (40.9)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	14 (0.2)	0	0 (0.0)	14 (0.2)	0	0 (0.0)	43 (39.1)	0	0 (0.0)	0 (0.0)	3111 (41.0)	0	0 (0.0)	0 (0.0)	3154 (40.9)	0	0 (0.0)	0	0 (0.0)	3154 (40.9)	0	0 (0.0)																				
Pyrexia	40 (36.4)	0	0 (0.0)	0 (0.0)	3057 (40.2)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	8 (0.1)	0	0 (0.0)	8 (0.1)	0	0 (0.0)	40 (36.4)	0	0 (0.0)	0 (0.0)	3063 (40.3)	0	0 (0.0)	0 (0.0)	3101 (40.2)	0	0 (0.0)	0	0 (0.0)	3101 (40.2)	0	0 (0.0)																				
Chills	18 (16.4)	0	0 (0.0)	0 (0.0)	1380 (18.2)	0	0 (0.0)	0 (0.0)	1	0 (0.0)	0	0 (0.0)	5 (0.1)	0	0 (0.0)	5 (0.1)	0	0 (0.0)	18 (16.4)	0	0 (0.0)	0 (0.0)	1382 (18.2)	0	0 (0.0)	0 (0.0)	1400 (18.2)	0	0 (0.0)	0	0 (0.0)	1400 (18.2)	0	0 (0.0)																				
Vaccination site pruritus	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	6 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	216 (2.8)	0	0 (0.0)	222 (2.9)	0	0 (0.0)	6 (0.5)	0	0 (0.0)	0 (0.0)	216 (2.8)	0	0 (0.0)	0 (0.0)	222 (2.9)	0	0 (0.0)	0	0 (0.0)	222 (2.9)	0	0 (0.0)																				
Malaise	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	44 (0.6)	0	0 (0.0)	44 (0.6)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	44 (0.6)	0	0 (0.0)	0 (0.0)	44 (0.6)	0	0 (0.0)	0	0 (0.0)	44 (0.6)	0	0 (0.0)																				
Chest pain	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	13 (0.2)	0	0 (0.0)	13 (0.2)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	13 (0.2)	0	0 (0.0)	0 (0.0)	13 (0.2)	0	0 (0.0)	0	0 (0.0)	13 (0.2)	0	0 (0.0)																				
Pain	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	12 (0.2)	0	0 (0.0)	12 (0.2)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	12 (0.2)	0	0 (0.0)	0 (0.0)	12 (0.2)	0	0 (0.0)	0	0 (0.0)	12 (0.2)	0	0 (0.0)																				
Vaccination site warmth	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	12 (0.2)	0	0 (0.0)	12 (0.2)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	12 (0.2)	0	0 (0.0)	0 (0.0)	12 (0.2)	0	0 (0.0)	0	0 (0.0)	12 (0.2)	0	0 (0.0)																				
Axillary pain	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	11 (0.1)	0	0 (0.0)	11 (0.1)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	11 (0.1)	0	0 (0.0)	0 (0.0)	11 (0.1)	0	0 (0.0)	0	0 (0.0)	11 (0.1)	0	0 (0.0)																				
Feeling abnormal	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	7 (0.1)	0	0 (0.0)	7 (0.1)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	7 (0.1)	0	0 (0.0)	0 (0.0)	7 (0.1)	0	0 (0.0)	0	0 (0.0)	7 (0.1)	0	0 (0.0)																				
Swelling	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	7 (0.1)	0	0 (0.0)	7 (0.1)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	7 (0.1)	0	0 (0.0)	0 (0.0)	7 (0.1)	0	0 (0.0)	0	0 (0.0)	7 (0.1)	0	0 (0.0)																				
Thirst	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	6 (0.1)	0	0 (0.0)	6 (0.1)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	6 (0.1)	0	0 (0.0)	0 (0.0)	6 (0.1)	0	0 (0.0)	0	0 (0.0)	6 (0.1)	0	0 (0.0)																				
Asthenia	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	5 (0.1)	0	0 (0.0)	5 (0.1)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	5 (0.1)	0	0 (0.0)	0 (0.0)	5 (0.1)	0	0 (0.0)	0	0 (0.0)	5 (0.1)	0	0 (0.0)																				
Feeling hot	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	5 (0.1)	0	0 (0.0)	5 (0.1)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	5 (0.1)	0	0 (0.0)	0 (0.0)	5 (0.1)	0	0 (0.0)	0	0 (0.0)	5 (0.1)	0	0 (0.0)																				
Peripheral swelling	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	4 (0.1)	0	0 (0.0)	4 (0.1)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	4 (0.1)	0	0 (0.0)	0 (0.0)	4 (0.1)	0	0 (0.0)	0	0 (0.0)	4 (0.1)	0	0 (0.0)																				
Oedema peripheral	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	3 (0.0)	0	0 (0.0)	0 (0.0)	3 (0.0)	0	0 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)																				
Vaccination site induration	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	3 (0.0)	0	0 (0.0)	0 (0.0)	3 (0.0)	0	0 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)																				
Vaccination site discoloration	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	3 (0.0)	0	0 (0.0)	0 (0.0)	3 (0.0)	0	0 (0.0)	0	0 (0.0)	3 (0.0)	0	0 (0.0)																				
Confluent aggravated	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)																				
Feeling cold	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)																				
Swelling face	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)																				
Vaccination site burning	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)																				
Vaccination site eczema	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0 (0.0)	2 (0.0)	0	0 (0.0)	0	0 (0.0)	2 (0.0)	0	0 (0.0)																				
Discomfort	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)																				
Facial pain	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)																				
Injection site paresthesia	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)																				
Muscle	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)																				
Injected limb mobility decreased	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)																				
Vaccination site reaction	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)																				
Vaccination site haemorrhage	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0 (0.0)	1 (0.0)	0	0 (0.0)	0	0 (0.0)	1 (0.0)	0	0 (0.0)																				

As of Sep 8, 2025

As of Sep 8, 2025

162/196

Table 17-1 Incidence of ADRs in subjects with special vaccinee backgrounds (renal impairment)

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Solicited adverse events																	
	Renal impairment									Unselected adverse events								
	Yes			No			Total			Yes			No			Total		
	Total	1/0	Serious	Total	1/0	Serious	Total	1/0	Serious	Total	1/0	Serious	Total	1/0	Serious	Total	1/0	Serious
Number of subjects with ADRs	90	0	0	6304	0	0	6394	0	0	14	0	0	740	0	0	754	0	0
Incidence proportion of ADRs (%)	81.1	0.0	0.0	615.9	0.0	0.0	6312.7	0.0	0.0	12.7	0.0	0.0	97.7	0.0	0.0	92.7	0.0	0.0
Type of ADR	Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)		
Ear and labyrinth disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	15	(0.2)	0	(0.0)	0	(0.0)
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)
Ear pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)
Ear discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)
Hypoaacusis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Ear pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Eye disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)	1	(0.0)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)
Eye discharge	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Eye pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Periorbital swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Eye inflammation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Retinal haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)
Swelling of eyelid	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vision blurred	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Visual acuity reduced	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Cyclical irritation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Eye/eyelid pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)	1	(0.0)	0	(0.0)
Peripheral oedema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)
Hot flush	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)
Hypertension	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Flushing	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Hypertension	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Internal haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Infectious and infestations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	(0.2)	0	(0.0)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)
Rhinitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Conjunctivitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Gastroenteritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Gastroenteritis viral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Herpes virus infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Herpes zoster	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Pustule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Cystitis bacterial	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Candida disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.2)	0	(0.0)	0	(0.0)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.2)	0	(0.0)	0	(0.0)
Renal and urinary disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)
Poliuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)
Nocturia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)
Haematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Polymia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Urethral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)	0	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Psychiatric disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	1	(0.0)	4	(0.1)
Dissociative disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Euphoric mood	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Hallucination	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)
Lactose	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Injury, poisoning and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heat illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

Note) If the onset date of an ADR was unknown and solicited/unselected status could not be determined, the ADR was counted only in the combined total.

MedDRA/J (28.0)

Subjects included in safety analysis

164/196

Table 17-2 Outcome of ADRs in subjects with special vaccinee backgrounds (renal impairment)

Subjects included in safety analysis

Sample size	Renal impairment																			
	Selected adverse events																			
	Yes																			
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Unknown	
Number of subjects with ADRs	0	0	0	110	3	87	0	0	0	797	461	5842	1	0	0	0	797	464	5929	1
Type of ADR	Number of subjects with ADRs (%)																			
Constitutional disorders	0	(0.0)	0	(0.0)	0	(0.0)	11	(10.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain	0	(0.0)	0	(0.0)	6	(5.5)	6	(5.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(1.2)	2	(0.0)
Abdominal pain upper	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cheilitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	0	(0.0)	0	(0.0)	0	(0.0)	6	(5.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gingival pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Melasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	0	(0.0)	0	(0.0)	0	(0.0)	7	(6.4)	0	(0.0)	0	(0.0)	14	(1.2)	356	(44.7)	0	(0.0)	14	(1.2)
Oral discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Salivary gland pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Stomatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue rough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Toothache	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vomiting	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.6)	0	(0.0)	0	(0.0)	1	(0.0)	76	(11.0)	0	(0.0)	1	(0.0)
Lip blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoaesthesia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Parosmia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue exfoliation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosa erosion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Loose tooth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Facies soft	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Anal incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosal roughening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Erythema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pain of skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Perioral dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash erythematous	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash pruritic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Scall	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin discolouration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin burning sensation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Butterfly rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Circumoral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders	0	(0.0)	0	(0.0)	2	(1.8)	43	(39.1)	0	(0.0)	0	(0.0)	137	(11.5)	2905	(36.6)	2	(0.0)	139	(11.6)
Arthralgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Back pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bone pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Flank pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Groin pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle weakness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	2	(1.8)	43	(39.1)	0	(0.0)	0	(0.0)	137	(11.5)	2905	(36.6)	2	(0.0)	139	(11.6)
Pain in extremity	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

Table 17-2 Outcome of ADRs in subjects with special vaccinee backgrounds (renal impairment)

Subjects included in safety analysis

Sample size	Renal impairment																			
	Selected adverse events																			
	Yes										No									
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown		
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				
Total																				
464																				
3929																				
1																				
Unknown																				
Number of subjects with ADRs (%)																				

If multiple events with the same PT occur in the same subject, the events will be tabulated based on the following priority: (1) Serious > Non-serious, and (2) Death > Recovered with sequelae > Not recovered > Recovering > Recovered > Unknown.
Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Subjects included in safety analysis

167/196

Subjects included in safety analysis

[illegible]

Table 17-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Known impairment																			
	Unidentified adverse events																			
	Yes										No									
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Unknown
Number of subjects with ADRs	0	0	0	1/0	2	12	0	0	0	0	7/07	4/0	10/0	2	0	0	0	7/07	3/1	3/01
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)									
Head and sensory disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Headache	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nosuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Poliakuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	4	(0.1)
Poluria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
General disorders and administration site conditions	0	(0.0)	0	(0.0)	2	(1.8)	6	(5.5)	0	(0.0)	0	(0.0)	13	(0.2)	340	(4.5)	2	(0.0)	0	(0.0)
Aches	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	11	(0.1)	1	(0.0)	0	(0.0)
Chills	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)	0	(0.0)	7	(0.1)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	5	(0.1)
Injection site paronychia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	40	(0.5)	1	(0.0)	0	(0.0)
Mus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)	1	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	11	(0.1)	0	(0.0)	11	(0.1)
Pruritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)	0	(0.0)	8	(0.1)
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	7	(0.1)
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	6	(0.1)
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	10	(0.1)	0	(0.0)	10	(0.1)
Peripneal swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	4	(0.1)
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site erythema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	(0.2)	0	(0.0)	0	(0.0)	13	(0.2)
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Vaccination site pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	16	(0.2)	0	(0.0)	0	(0.0)	16	(0.2)
Vaccination site pruritis	0	(0.0)	0	(0.0)	2	(1.8)	4	(3.6)	0	(0.0)	0	(0.0)	3	(0.0)	213	(2.8)	0	(0.0)	5	(0.1)
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Vaccination site haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Vaccination site swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	0	(0.0)	0	(0.0)	11	(0.1)
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	10	(0.1)	0	(0.0)	10	(0.1)
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	6	(0.1)	0	(0.0)	1	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heavy, postoperative and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)

If multiple events with the same PT occur in the same sub
Note) If the onset date of an ADR was unknown and odds

Subjects included in safety analysis

Table 17-2

Table 17-2 Outcome of ADRs in subjects with special va

As of Sep 8, 2025

Subjects included in safety analysis

Sample size	Fatal impairment																					
	Confirmed fatal										Recovering											
	Death										Recovering with sequelae											
	Not recovered										Recovered											
Number of subjects with ADRs	119										797											
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)											
Constitutional disorders	0	(0.0)	0	(0.0)	0	(0.0)	13	(11.8)	0	(0.0)	0	(0.0)	0	(0.0)	28	(3.4)	726	(9.0)	0	(0.0)	0	(0.0)
Abdominal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	0	(0.0)	9	(0.1)
Abdominal pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	6	(5.5)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	10	(0.1)	2	(0.0)
Abdominal pain upper	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	0	(0.0)	11	(0.1)
Cheilitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Diarrhoea	0	(0.0)	0	(0.0)	0	(0.0)	6	(5.5)	0	(0.0)	0	(0.0)	0	(0.0)	17	(0.2)	334	(4.4)	0	(0.0)	17	(0.2)
Gingival pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Melasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	0	(0.0)	0	(0.0)	0	(0.0)	7	(6.4)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)	360	(4.7)	0	(0.0)	14	(0.2)
Oral discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Salivary gland pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Stomatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tongue rough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Toothache	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vomiting	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	79	(1.0)	0	(0.0)	1	(0.0)
Lip blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Hypoaesthesia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Parosmia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Tongue exfoliation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosa erosion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Loose tooth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Facies soft	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Anal incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Oral mucosal roughening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.7)	0	(0.0)	0	(0.0)	0	(0.0)	16	(0.2)	145	(1.9)	0	(0.0)	16	(0.2)
Blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Erythema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	0	(0.0)	9	(0.1)
Night sweats	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pain of skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Perioral dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Purpura	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	95	(1.3)	0	(0.0)	10	(0.1)
Rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash erythematous	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	19	(0.3)	0	(0.0)	2	(0.0)
Rash pruritic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Scab	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Skin discolouration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Skin tightness	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	8	(0.1)	1	(0.0)	5	(0.1)
Skin induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin burning sensation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Butterfly rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Circumoral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.8)	43	(35.1)	0	(0.0)	0	(0.0)	2	(0.0)	294	(3.7)	0	(0.0)	2	(0.0)
Arthralgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	84	(1.1)	0	(0.0)	84	(1.1)
Back pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	32	(0.4)	0	(0.0)	2	(0.0)
Bone pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Flank pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Groin pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)
Muscle weakness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)
Myalgia	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.8)	43	(35.1)	0	(0.0)	0	(0.0)	137	(1.8)	294	(3.7)	2	(0.0)	139	(1.8)
Neck pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pain in extremity	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)	1	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.2)	0	(0.0)	12	(0.2)

Table 17-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Known impairment																			Total																		
	Confirmed total																																					
	Yes									No									Recovering									Unknown										
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown														
0	0	0	110	3	88	0	0	0	7997	481	5801	1	0	0	0	0	7997	486	5919	1	0	0	0															
Number of subjects with ADRs	0	0	0	110	3	88	0	0	0	7997	481	5801	1	0	0	0	0	7997	486	5919	1	0	0	0														
Type of ADR	Number of subjects with ADRs (%)												Number of subjects with ADRs (%)																									
Head and sensory disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)														
Hemicrania	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)														
Nocutanea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)														
Polakiuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)														
Polyuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Urinary pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
General disorders and administration site conditions	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)														
Aches	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)														
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	1	(0.0)														
Chills	0	(0.0)	0	(0.0)	1	(0.9)	17	(15.5)	0	(0.0)	41	(0.5)	1340	(17.6)	1	(0.0)	0	(0.0)	0	(0.0)	42	(0.5)	1357	(17.6)														
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)														
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)														
Fatigue	0	(0.0)	0	(0.0)	1	(0.9)	42	(38.2)	0	(0.0)	134	(1.8)	2975	(39.2)	2	(0.0)	0	(0.0)	0	(0.0)	135	(1.8)	3017	(39.1)														
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)														
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)														
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)														
Injection site paronychia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	40	(0.5)	1	(0.0)	0	(0.0)	0	(0.0)	40	(0.5)	1	(0.0)														
Muscle	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)														
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	11	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	0	(0.0)														
Pruritus	0	(0.0)	0	(0.0)	1	(0.9)	39	(35.5)	0	(0.0)	121	(1.6)	2999	(38.7)	1	(0.0)	0	(0.0)	0	(0.0)	122	(1.6)	2978	(38.6)														
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)														
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)														
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)														
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)														
Femoral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)														
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Vaccination site erythema	0	(0.0)	0	(0.0)	2	(1.8)	45	(40.9)	0	(0.0)	206	(2.7)	3816	(50.2)	1	(0.0)	0	(0.0)	0	(0.0)	208	(2.7)	3861	(50.1)														
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)														
Vaccination site pain	0	(0.0)	0	(0.0)	2	(1.8)	81	(73.6)	0	(0.0)	287	(3.8)	5699	(77.0)	1	(0.0)	0	(0.0)	0	(0.0)	289	(3.7)	5710	(77.0)														
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	213	(2.8)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	217	(2.8)														
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)														
Vaccination site haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Vaccination site swelling	0	(0.0)	0	(0.0)	3	(2.7)	46	(41.8)	0	(0.0)	198	(2.6)	3943	(51.9)	1	(0.0)	0	(0.0)	0	(0.0)	201	(2.6)	3989	(51.8)														
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)														
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)														
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)														
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)														
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Signs, symptoms and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)														

If multiple events with the same PT occur in the same sub
Note) If the onset date of an ADR was unknown and odds

MacDR.A.1 (28.0)

Table 18-1 Incidence of ADRs in subjects with special vaccinee backgrounds (hepatic impairment)

As of Sep 8, 2025

Subjects included in safety analysis

Sample size	Solicited adverse events												Unsolicited adverse events												Continued total											
	Yes						No						Yes						No						Yes						No					
	Total		Yes		Serious		Total		Yes		Serious		Total		Yes		Serious		Total		Yes		Serious		Total		Yes		Serious							
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%						
Number of subjects with ADRs (%)	142	85.3	0	0	6252	82.9	0	0	6394	83.0	0	0	31	18.3	0	0	723	9.6	0	0	754	9.6	0	0	142	85.3	0	0	6252	83.1	0	0	6394	83.1	0	0
Number of subjects with ADRs (%)	142	(85.3)	0	(0.0)	6252	(82.5)	0	(0.0)	6362	(82.5)	0	(0.0)	19	(11.4)	0	(0.0)	345	(4.6)	0	(0.0)	364	(4.7)	0	(0.0)	142	(85.3)	0	(0.0)	6223	(82.5)	0	(0.0)	6365	(82.6)	0	(0.0)
General disorders and administration site conditions	142	(85.3)	0	(0.0)	6252	(82.5)	0	(0.0)	6362	(82.5)	0	(0.0)	19	(11.4)	0	(0.0)	345	(4.6)	0	(0.0)	364	(4.7)	0	(0.0)	142	(85.3)	0	(0.0)	6223	(82.5)	0	(0.0)	6365	(82.6)	0	(0.0)
Vaccination site pain	135	(81.3)	0	(0.0)	5902	(78.1)	0	(0.0)	6067	(78.7)	0	(0.0)	8	(4.8)	0	(0.0)	16	(0.2)	0	(0.0)	16	(0.2)	0	(0.0)	135	(81.3)	0	(0.0)	5905	(78.2)	0	(0.0)	6069	(78.8)	0	(0.0)
Vaccination site swelling	94	(56.6)	0	(0.0)	4094	(54.3)	0	(0.0)	4188	(54.3)	0	(0.0)	11	(6.1)	0	(0.0)	11	(0.1)	0	(0.0)	94	(56.6)	0	(0.0)	4097	(54.1)	0	(0.0)	4191	(54.6)	0	(0.0)	4200	(54.8)	0	(0.0)
Vaccination site erythema	94	(56.6)	0	(0.0)	3973	(52.7)	0	(0.0)	4067	(52.8)	0	(0.0)	1	(0.6)	0	(0.0)	13	(0.2)	0	(0.0)	94	(56.6)	0	(0.0)	3976	(52.7)	0	(0.0)	4070	(52.8)	0	(0.0)	4180	(54.2)	0	(0.0)
Fatigue	75	(45.2)	0	(0.0)	3074	(40.9)	0	(0.0)	3149	(40.9)	0	(0.0)	1	(0.6)	0	(0.0)	13	(0.2)	0	(0.0)	75	(45.2)	0	(0.0)	3079	(40.9)	0	(0.0)	3144	(40.9)	0	(0.0)	3154	(40.9)	0	(0.0)
Pyrexia	61	(36.7)	0	(0.0)	3036	(40.3)	0	(0.0)	3097	(40.2)	0	(0.0)	1	(0.6)	0	(0.0)	7	(0.1)	0	(0.0)	61	(36.7)	0	(0.0)	3040	(40.3)	0	(0.0)	3101	(40.2)	0	(0.0)	3112	(40.2)	0	(0.0)
Chills	31	(18.7)	0	(0.0)	1367	(18.1)	0	(0.0)	1398	(18.1)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	31	(18.7)	0	(0.0)	1369	(18.2)	0	(0.0)	1400	(18.2)	0	(0.0)	1411	(18.2)	0	(0.0)
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(5.4)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	213	(2.8)	0	(0.0)	222	(2.8)	0	(0.0)	231	(2.8)	0	(0.0)
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.0)	0	(0.0)	44	(0.6)	0	(0.0)	5	(3.0)	0	(0.0)	39	(0.5)	0	(0.0)	44	(0.6)	0	(0.0)	44	(0.6)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	(8.2)	0	(0.0)	11	(0.1)	0	(0.0)	12	(0.2)	0	(0.0)	11	(0.1)	0	(0.0)	11	(0.1)	0	(0.0)	12	(0.2)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	11	(0.2)	0	(0.0)	1	(0.6)	0	(0.0)	11	(0.1)	0	(0.0)	11	(0.1)	0	(0.0)	12	(0.2)	0	(0.0)
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.2)	0	(0.0)	12	(0.2)	0	(0.0)	2	(1.2)	0	(0.0)	10	(0.1)	0	(0.0)	10	(0.1)	0	(0.0)	12	(0.2)	0	(0.0)
Axillary pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(6.1)	0	(0.0)	11	(0.1)	0	(0.0)	7	(4.1)	0	(0.0)	11	(0.1)	0	(0.0)	11	(0.1)	0	(0.0)	12	(0.2)	0	(0.0)
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(4.1)	0	(0.0)	7	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	7	(0.1)	0	(0.0)	1	(0.6)	0	(0.0)	6	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(3.1)	0	(0.0)	6	(0.1)	0	(0.0)	6	(0.1)	0	(0.0)	6	(0.1)	0	(0.0)	6	(0.1)	0	(0.0)	6	(0.1)	0	(0.0)
Asthenia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.1)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(2.1)	0	(0.0)	5	(0.1)	0	(0.0)	4	(2.1)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(2.1)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Vaccination site eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Injection site paresthesia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Muscle	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders	72	(43.4)	0	(0.0)	3047	(40.4)	0	(0.0)	3119	(40.5)	0	(0.0)	5	(3.0)	0	(0.0)	160	(2.1)	1	(0.0)	165	(2.1)	1	(0.0)	72	(43.4)	0	(0.0)	3052	(40.5)	0	(0.0)	3125	(40.5)	0	(0.0)
Myalgia	72	(43.4)	0	(0.0)	30																															

Table 18-1 Incidence of ADRs in subjects with special vaccinee backgrounds (hepatic impairment)

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Hepatic impairment															Continued from page 1														
	Unspecified adverse events															Continued from page 1														
	Yes			No			Total			Yes			No			Total			Yes			No			Total					
	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total					
142	142	0	6252	6252	0	6394	31	0	723	723	0	754	142	0	6366	142	0	6252	6252	0	6394	31	0	723	723	0	754			
85.3	85.3	0	82.9	82.9	0	83.0	18.3	0	16.6	16.6	0	17.9	85.3	0	85.1	85.3	0	85.9	85.9	0	86.0	18.3	0	16.6	16.6	0	17.9			
Incidence proportion of ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs (%)																														
Number of subjects with ADRs																														

Table 18-1 Incidence of ADRs in subjects with special vaccinee backgrounds (hepatic impairment)

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Solicited adverse events																	
	Hepatic impairment									Unselected adverse events								
	Yes			No			Total			Yes			No			Total		
	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious	Total	Yes	Serious
Number of subjects with ADRs	142	0	0	6252	0	0	6394	0	0	31	0	0	723	0	0	754	0	0
Incidence proportion of ADRs (%)	85.5	0.0	0.0	82.9	0.0	0.0	83.6	0.0	0.0	18.3	0.0	0.0	9.8	0.0	0.0	82.9	0.0	0.0
Type of ADR	Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)			Number of subjects with ADRs (%)		
Ear and labyrinth disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	15	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	6	(0.1)
Ear pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Ear discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Hypoaacus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Ear pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Eye disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)	1	(0.0)	14	(0.2)	1	(0.0)
Eye pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)
Eye discharge	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Eye pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Periorbital swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Eye inflammation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Retinal haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Swelling of eyelid	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vision blurred	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Visual acuity reduced	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Cyclical irritation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Eye/eye pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vascular disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	13	(0.2)	1	(0.0)	14	(0.2)	1	(0.0)
Peripheral edema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	5	(0.1)	0	(0.0)
Hot flush	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)
Hypertension	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Flushing	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Hypertension	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Internal haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)
Infections and infestations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	(0.2)	0	(0.0)	13	(0.2)	0	(0.0)
Oral herpes	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)
Rhinitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Conjunctivitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Gastroenteritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Gastroenteritis viral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Herpes virus infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Herpes zoster	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Pustule	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Cystitis bacterial	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Candida disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.2)	0	(0.0)	12	(0.2)	0	(0.0)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.2)	0	(0.0)	12	(0.2)	0	(0.0)
Renal and urinary disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	10	(0.1)	0	(0.0)
Poliuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)	0	(0.0)
Nocturia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)
Haematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Polymia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Urethral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)	7	(0.1)	0	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Psychiatric disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	1	(0.0)	4	(0.1)	1	(0.0)
Dissociative disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Euphoric mood	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Hallucination	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Lactose	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Injury, poisoning and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Head illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

Note) If the onset date of an ADR was unknown and solicited/unselected status could not be determined, the ADR was counted only in the combined total.

MedDRA/J (28.0)

Table 18-2 Outcome of ADRs in subjects with special vaccinee backgrounds (hepatic impairment)

Subjects included in safety analysis

			Hepatic impairment																																			
			Selected adverse events																																			
			Yes									No																										
Death			Recovered with sequelae			Not recovered			Recovering			Recovered			Unknown			Death			Recovered with sequelae			Not recovered			Recovering			Recovered			Unknown					
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0			0			0			0			0			0			0		
0			0			0			0			0			0			0</																				

Table 18-2 Outcome of ADRs in subjects with special vaccinee backgrounds (hepatic impairment)

Subjects included in safety analysis

Sample size	Hepatic impairment																		
	Selected adverse events																		
	Yes									No									Total
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	
Number of subjects with ADRs (%)	0	0	0	4	138	0	0	0	7941	4601	3791	1	0	0	0	464	3929	1	
Type of ADR	Number of subjects with ADRs (%)									Number of subjects with ADRs (%)									Total
Death and serious disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Haematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Nosuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Polakiuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Pyuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Urinary pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
General disorders and administration site conditions	0	(0.0)	0	(0.0)	4	(2.4)	138	(83.1)	0	(0.0)	0	(0.0)	424	(5.6)	3795	(76.8)	1	(0.0)	
Aches	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Chills	0	(0.0)	0	(0.0)	0	(0.0)	31	(18.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	42	(1.2)	
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	74	(44.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Injection site paronychia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Pruritis	0	(0.0)	0	(0.0)	0	(0.0)	61	(36.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	122	(1.6)	
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Periphereal swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site erythema	0	(0.0)	0	(0.0)	1	(0.6)	93	(56.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	208	(2.7)	
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site pain	0	(0.0)	0	(0.0)	3	(1.8)	132	(79.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	289	(3.7)	
Vaccination site pruritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site swelling	0	(0.0)	0	(0.0)	2	(1.2)	92	(55.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	201	(2.6)	
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heavy, posturing and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	

If multiple events with the same PT occur in the same subject, the events will be tabulated based on the following priority: (1) Serious > Non-serious, and (2) Death > Recovered with sequelae > Not recovered > Recovering > Recovered > Unknown.
Note) If the onset date of an ADR was unknown and solicited/unselected status could not be determined, the ADR was counted only in the combined total.

Table 18-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size Number of subjects with ADRs		Hepatic impairment																			
		Unidentified adverse events																			
		Yes										No									
		Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown		
0	0	0	0	1	30	0	0	0	7/41	30	6/41	2	0	0	7/40	31	0	0			
Type of ADR		Number of subjects with ADRs (%)										Number of subjects with ADRs (%)									
Infections and infestations		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	11 (31.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Conjunctivitis		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)		
Gastroenteritis		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Gastroenteritis viral		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)		
Herpes virus infection		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Herpes zoster		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		
Papule		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		
Chlamydia		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		
Cystitis bacterial		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)		
Oral herpes		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (31.1)	11 (31.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Blood and lymphatic system disorders		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	19 (55.9)	19 (55.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Lymph node pain		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (11.1)	4 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Lymphadenopathy		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	15 (42.9)	15 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	15 (42.9)	15 (42.9)	0 (0.0)		
Metabolism and nutrition disorders		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	24 (68.3)	24 (68.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Decreased appetite		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	24 (68.3)	24 (68.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Psychiatric disorders		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	3 (0.0)	0 (0.0)		
Dissociative disorder		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Euphoric mood		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Hallucination		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Lethargy		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Nervous system disorders		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (11.8)	3 (11.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (0.0)	90 (1.2)	30 (4.4)	1 (0.0)	0 (0.0)	9 (1.2)	1 (0.0)		
Dizziness		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	30 (4.4)	30 (4.4)	0 (0.0)	0 (0.0)	3 (0.0)	0 (0.0)		
Dizziness postural		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Dyspareunia		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)		
Dysgeusia		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Head discomfort		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Headache		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Hypoesthesia		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	10 (0.0)	10 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Migraine		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Movement disorder		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Neuralgia		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Parosmia		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (0.0)	9 (0.0)	1 (0.0)	1 (0.0)	9 (0.0)	9 (0.0)	0 (0.0)		
Parosmia		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Peripheral nerve palsy		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Somnolence		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	18 (0.0)	18 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Tremor		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Balance disorder		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	5 (0.0)	5 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	5 (0.0)	0 (0.0)		
Taste disorder		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Brain fog		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Eye disorders		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Eye discharge		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Eye inflammation		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Eye irritation		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Eye pain		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Retinal hemorrhage		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Swelling of eyelid		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Vision blurred		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Visual acuity reduced		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Eye pruritus		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)	2 (0.0)	0 (0.0)		
Periorbital swelling		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Eyelid redness		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Ear and labyrinth disorders		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (0.0)	14 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Ear pain		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.0)	4 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Tinnitus		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (0.0)	6 (0.0)	6 (0.0)	6 (0.0)	0 (0.0)	6 (0.0)	6 (0.0)	0 (0.0)		
Hypacusis		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)	1 (0.0)	1 (0.0)	0 (0.0)		
Ear discomfort		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	3 (0.0)	0 (0.0)	0 (0.0)	3 (0.0)	3 (0.0)	0 (0.0)		
Ear ringing		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0 (												

Table 18-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Hepatic impairment																			
	Unidentified adverse events																			
	Yes																			
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Unknown	
Number of subjects with ADRs	0	0	0	1	30	0	0	0	0	7941	30	0	0	0	7941	31	301	2		
Type of ADR	Number of subjects with ADRs (%)																			
Constitutional disorders	0	(0.0)	0	(0.0)	2	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	61	(0.8)	1	(0.0)	0	(0.0)
Abdominal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain upper	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	11	(0.1)
Cheilitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Diarrhoea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)	8	(0.1)
Gingival pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Glossitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Melasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Nausea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)
Oral discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Oral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Salivary gland pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Stomatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)	0	(0.0)	9	(0.1)
Tongue rough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Toothache	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	1	(0.0)	2	(0.0)
Vomiting	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	3	(0.0)
Lip blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Hypoaesthesia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Parosmia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Tongue exfoliation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Oral mucosa erosion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Loose tooth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Faces soft	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Anal incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Oral mucosal roughening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Skin and subcutaneous tissue disorders	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	8	(4.8)	0	(0.0)	0	(0.0)	15	(0.2)	137	(1.8)	1	(0.0)
Blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Dermatitis contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)	9	(0.1)
Erythema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	11	(0.1)
Night sweats	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Pain of skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	2	(0.0)	4	(0.0)
Perioral dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Pruritus	0	(0.0)	0	(0.0)	1	(4.1)	0	(0.0)	7	(4.2)	0	(0.0)	9	(0.1)	89	(1.2)	0	(0.0)	100	(1.2)
Purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	19	(0.3)	20	(0.3)
Rash erythematous	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Rash pruritic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Scab	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Skin discolouration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Urticaria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	9	(0.1)	1	(0.0)
Skin tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Skin induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Skin burning sensation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	2	(0.0)
Butterfly rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Musculoskeletal and connective tissue disorders	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	155	(2.0)	0	(0.0)
Arthralgia	0	(0.0)	0	(0.0)	0	(0.0)	4	(2.4)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	80	(1.1)	0	(0.0)
Back pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	31	(0.4)	0	(0.0)
Bone pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	1	(0.0)
Flank pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Groin pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Muscle spasms	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	6	(0.1)
Muscle weakness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	4	(0.1)	0	(0.0)	4	(0.1)
Myalgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	9	(0.1)	0	(0.0)	10	(0.1)
Neck pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)	0	(0.0)
Pain in extremity	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)	0	(0.0)	15	(0.2)
Neck pain anterior	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	1	(0.0)
Muscle tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	2	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal joint pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	12	(0.2)	0	(0.0)	12	(0.2)

Table 18-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Hepatic impairment																			
	Unidentified adverse events										Fatal									
	Yes					No					Recovering					Recovering				
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae
Number of subjects with ADRs	0	0	0	1	30	0	0	0	0	7941	30	0	0	0	0	31	301	2	0	0
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)									
Respiratory and sensory disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fluorimetry	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nosuria	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Polyuria	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
General disorders and administration site conditions	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aches	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Chest pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Chills	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Condition aggravated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Discomfort	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Facial pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fatigue	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feeling abnormal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feeling cold	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feeling hot	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Injection site paronychia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaise	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Muscle pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Oedema peripheral	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pruritus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swelling face	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Thirst	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Achilles pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Peripheral swelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Injected limb mobility decreased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site erythema	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site reaction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site induration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site pruritus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site discoloration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site haemorrhage	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site discomfort	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site rash	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site bruising	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site swelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site vesicles	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site warmth	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site exema	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site mass	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Investigations	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C-reactive protein increased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heart rate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heart rate increased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Oxygen saturation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Infusion, poisoning and procedural complications	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heart illness	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

If multiple events with the same PT occur in the same sub
 Note) If the onset date of an ADR was unknown and odds

As of Sep 8, 2025

As of Sep 8, 2025

Table 18-2

Table 18-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Hepatic impairment																					
	Combined total																					
	Yes										Fast										Total	
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown				
Number of subjects with ADRs	0	0	0	166	3	137	0	0	0	7941	481	3782	1	0	0	0	7907	486	3919	1		
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)										Number of subjects with ADRs (%)	
Renal and urinary disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)
Haematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Nocturia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Polakiuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Poluria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
General disorders and administration site conditions	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.0)	137	(82.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	433	(5.6)	5931	(77.0)
Aches	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	31	(18.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	42	(0.5)	1557	(17.6)
Chills	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	74	(44.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	135	(1.8)
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)
Injection site parasthesia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.0)	0	(0.0)	0	(0.0)	3	(0.0)	35	(0.5)	1	(0.0)	0	(0.0)	40	(0.5)
Mus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	0	(0.0)	0	(0.0)	11	(0.1)
Pruritis	0	(0.0)	0	(0.0)	0	(0.0)	41	(26.7)	0	(0.0)	0	(0.0)	122	(1.6)	2917	(38.7)	1	(0.0)	0	(0.0)	122	(1.6)
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	6	(0.1)
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site erythema	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	93	(56.0)	0	(0.0)	0	(0.0)	207	(2.7)	3768	(50.0)	1	(0.0)	0	(0.0)
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)
Vaccination site pain	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.8)	132	(79.5)	0	(0.0)	0	(0.0)	286	(3.8)	5648	(74.9)	1	(0.0)	0	(0.0)
Vaccination site pruritis	0	(0.0)	0	(0.0)	0	(0.0)	9	(5.4)	0	(0.0)	0	(0.0)	5	(0.1)	208	(2.8)	0	(0.0)	0	(0.0)	5	(0.1)
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
Vaccination site haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Vaccination site swelling	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.2)	92	(55.4)	0	(0.0)	0	(0.0)	199	(2.6)	3897	(51.7)	1	(0.0)	0	(0.0)
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.2)	0	(0.0)	0	(0.0)	2	(0.0)	8	(0.1)	0	(0.0)	0	(0.0)	20	(0.1)
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Injury, poisoning and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)

If multiple events with the same PT occur in the same sub
Note) If the onset date of an ADR was unknown and odds

MedDRA v 28.0y

Table 19-1 Incidence of ADRs in subjects with special vaccine backgrounds (immune abnormality)

Subjects included in safety analysis

As of Sep 8, 2025

Sample size Number of subjects with ADRs Incidence proportion of ADRs (%)	Solicited adverse events												Unspecified adverse events												Continued total																												
	Yes						No						Yes						No						Yes						No																						
	Total	1	0	Total	1	0	Total	1	0	Total	1	0	Total	1	0	Total	1	0	Total	1	0	Total	1	0	Total	1	0																										
	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0																										
616	90.2	0	0	5758	82.2	0	6394	97.0	0	115	0.2	0	639	0.1	0	754	0.1	0	636	0.0	0	5770	82.2	0	6400	97.1	0																										
90.8	0	0	0	82.0	0	0	97.4	0	0	16.4	0	0	91.0	0	0	97.8	0	0	96.6	0	0	82.4	0	0	97.3	0	0																										
Number of subjects with ADRs (%)																																																					
Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)																													
General disorders and administration site conditions						General disorders and administration site conditions						General disorders and administration site conditions						General disorders and administration site conditions						General disorders and administration site conditions																													
631 (89.9)						5791 (81.8)						6362 (82.5)						52 (7.4)						312 (4.5)						364 (4.7)						631 (89.9)						5734 (81.9)						6365 (82.6)					
Vaccination site pain						5467 (78.0)						6667 (78.7)						0 (0.0)						16 (0.2)						0 (0.0)						668 (83.5)						5473 (78.1)						670 (83.8)					
Vaccination site swelling						3746 (53.5)						4188 (54.3)						0 (0.0)						11 (0.2)						0 (0.0)						442 (63.0)						3749 (53.5)						4191 (54.4)					
Vaccination site erythema						3624 (51.7)						4067 (52.8)						1 (0.1)						12 (0.2)						0 (0.0)						443 (63.1)						3627 (51.8)						4070 (52.8)					
Fatigue						2854 (48.7)						3149 (48.9)						0 (0.0)						13 (0.2)						0 (0.0)						4209 (74.5)						2859 (48.9)						3149 (48.9)					
Pyrexia						2827 (48.4)						3097 (48.2)						2 (0.3)						6 (0.1)						0 (0.0)						271 (38.6)						2830 (48.4)						3101 (48.2)					
Chills						1264 (18.0)						1398 (18.1)						0 (0.0)						5 (0.1)						0 (0.0)						134 (19.1)						1266 (18.1)						1400 (18.2)					
Vaccination site pruritus						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.2)						0 (0.0)						39 (5.6)						183 (2.6)						0 (0.0)					
Malaise						0 (0.0)						0 (0.0)						0 (0.0)						3 (0.4)						0 (0.0)						0 (0.0)						44 (0.6)						44 (0.6)					
Chest pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)					
Pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						12 (0.2)						0 (0.0)					
Vaccination site warmth						0 (0.0)						0 (0.0)						0 (0.0)						4 (0.6)						0 (0.0)						4 (0.6)						8 (0.1)						0 (0.0)					
Axillary pain						0 (0.0)						0 (0.0)						0 (0.0)						19 (0.3)						0 (0.0)						0 (0.0)						11 (0.1)						0 (0.0)					
Feeling abnormal						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						7 (0.1)						0 (0.0)						7 (0.1)						0 (0.0)					
Swelling						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)						0 (0.0)						6 (0.1)						0 (0.0)						7 (0.1)					
Thirst						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						5 (0.1)						0 (0.0)						6 (0.1)					
Asthenia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						5 (0.1)						0 (0.0)						4 (0.1)					
Feeling hot						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)						0 (0.0)						5 (0.1)					
Peripheral swelling						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						4 (0.1)						0 (0.0)						4 (0.1)					
Oedema peripheral						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						3 (0.0)						0 (0.0)						3 (0.0)					
Vaccination site induration						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						3 (0.0)						0 (0.0)					
Vaccination site discoloration						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)						0 (0.0)						3 (0.0)					
Condition aggravated						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Feeling cold						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)						0 (0.0)					
Swelling face						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Vaccination site bruising						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Vaccination site eczema						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Discomfort						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Facial pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Injection site paresthesia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Muscle						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Injected limb mobility decreased						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Vaccination site reaction						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Vaccination site haematoma						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Vaccination site discomfort						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Vaccination site rash						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Vaccination site vesicles						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Vaccination site mass						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Musculoskeletal and connective tissue disorders						306 (43.6)						2813 (48.2)						3119 (48.5)						39 (2.8)						145 (2.1)						165 (2.1)						312 (44.4)						2849 (48.7)					
Myalgia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						12 (1.7)						0 (0.0)						74 (11.1)						86 (11.1)					
Arthralgia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						32 (0.5)						0 (0.0)						34 (0.4)						32 (0.5)					
Back pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						15 (0.2)						0 (0.0)						15 (0.2)					
Pain in extremity						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						15 (0.2)						0 (0.0)						15 (0.2)					
Musculoskeletal stiffness						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)						0 (0.0)						14 (0.2)					
Neck pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						10 (0.1)						0 (0.0)					
Muscle spasms						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)						0 (0.0)					
Musculoskeletal pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						5 (0.1)						0 (0.0)					
Muscular weakness						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)						0 (0.0)					
Muscle tightness						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Bone pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)						0 (0.0)					
Musculoskeletal chest pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)					
Task pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Groin pain						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Abdominal arthritis						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)					
Neovascular disorders						253 (36.0)						2282 (32.6)						2535 (32.9)						0 (0.0)						12 (1.7)						0 (0.0)						90 (13.1)						255 (36.3)					
Headache						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						253 (36.0)					
Dizziness						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2285 (32.6)					
Hypoaesthesia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						20 (0.3)					
Paresthesia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						10 (0.1)					
Balance disorder						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)					
Nausea						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						6 (0.1)					
Head discomfort						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						2 (0.0)					
Taste disorder						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.1)					
Brain fog						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)					
Dizziness postural						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Dysaesthesia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Dysgeusia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Migraine						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)					
Movement disorder						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)					
Parosmia						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)					
Peripheral nerve palsy						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						1 (0.0)					
Tremor						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)						0 (0.0)					

Table 19-1 Incidence of ADRs in subjects with special vaccinee backgrounds (immune abnormality)

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Solicited adverse events												Unsolicited adverse events												Unlabeled total																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					
	Yes						No						Yes						No						Yes						No						Total																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																									
	Total	1	0	0	0	0	Total	1	0	0	0	Total	1	0	0	0	Total	1	0	0	0	Total	1	0	0	0	Total	1	0	0	0	Total	1	0	0	0	Total	1	0	0	0																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																					
	616	90.2	0	0	0	0	7578	92.2	0	0	0	6394	83.1	0	0	0	0	115	90.2	0	0	0	639	83.1	0	0	0	0	754	90.2	0	0	0	636	83.1	0	0	0	6466	83.1	0	0	0																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
Incidence proportion of ADRs (%)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
Type of ADR	Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with ADRs (%)						Number of subjects with A					

Subjects included in safety analysis

[illegible]

Subjects included in safety analysis

[illegible]

Table 19-2 Outcome of ADRs in subjects with special vaccinee backgrounds (immune abnormality)

Subjects included in safety analysis

Sample size	Immune abnormality																		
	Selected adverse events																		
	Yes									No									Total
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Type of ADR	Number of subjects with ADRs (%)									Number of subjects with ADRs (%)									Total
Head and sensory disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Hematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Nosuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Polakiuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Pyuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Urinary pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
General disorders and administration site conditions	0	(0.0)	0	(0.0)	0	(0.0)	41	(5.8)	598	(84.0)	0	(0.0)	0	(0.0)	0	(0.0)	428	(5.6)	
Aches	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Chills	0	(0.0)	0	(0.0)	7	(1.0)	127	(18.1)	0	(0.0)	1228	(17.5)	1	(0.0)	0	(0.0)	1355	(17.6)	
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Fatigue	0	(0.0)	0	(0.0)	17	(2.4)	278	(39.6)	0	(0.0)	118	(1.7)	2734	(39.0)	2	(0.0)	0	(0.0)	
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Injection site paronychia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Mias	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Pruritus	0	(0.0)	0	(0.0)	15	(2.1)	255	(36.3)	0	(0.0)	107	(1.5)	2719	(38.8)	1	(0.0)	0	(0.0)	
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site erythema	0	(0.0)	0	(0.0)	21	(3.0)	422	(60.1)	0	(0.0)	187	(2.7)	3436	(49.1)	1	(0.0)	0	(0.0)	
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site pain	0	(0.0)	0	(0.0)	28	(4.0)	572	(81.5)	0	(0.0)	261	(3.7)	5205	(74.3)	1	(0.0)	0	(0.0)	
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site swelling	0	(0.0)	0	(0.0)	18	(2.6)	424	(60.4)	0	(0.0)	183	(2.6)	3562	(50.8)	1	(0.0)	0	(0.0)	
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heavy, posturing and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	

If multiple events with the same PT occur in the same subject, the events will be tabulated based on the following priority: (1) Serious > Non-serious, and (2) Death > Recovered with sequelae > Not recovered > Recovering > Recovered > Unknown.
 Note) If the onset date of an ADR was unknown and solicited/unsolicited status could not be determined, the ADR was counted only in the combined total.

Subjects included in safety analysis

[illegible]

Table 19-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Immune abnormality																			
	Unidentified adverse events																			
	Yes																			
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Unknown	
0	0	0	12	10	0	0	0	0	0	39	308	2	0	0	0	700	30	308	2	
Number of subjects with ADRs (%)	Number of subjects with ADRs (%)																			
Constitutional disorders	0	(0.0)	0	(0.0)	0	(0.0)	10	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	53	(0.8)	1	(0.0)
Abdominal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Abdominal pain upper	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	0	(0.0)
Cheilitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Diarrhoea	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)
Gingival pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Melasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Nausea	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)
Oral discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Salivary gland pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Stomatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)
Tongue rough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Toothache	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)
Vomiting	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Lip blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Hypoaesthesia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Parosmia oral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Tongue exfoliation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Oral mucosa erosion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Loose tooth	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Facies soft	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Anal incontinence	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral mucosal roughening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders	0	(0.0)	0	(0.0)	4	(0.0)	31	(4.3)	0	(0.0)	0	(0.0)	12	(0.2)	112	(1.6)	1	(0.0)	0	(0.0)
Blister	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	16	(0.2)
Dermatitis contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Erythema	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)
Night sweats	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Pain of skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Perioral dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Pruritus	0	(0.0)	0	(0.0)	2	(0.3)	27	(3.8)	0	(0.0)	0	(0.0)	8	(0.1)	69	(1.0)	0	(0.0)	10	(0.1)
Purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Rash	0	(0.0)	0	(0.0)	1	(0.1)	3	(0.4)	0	(0.0)	0	(0.0)	1	(0.0)	16	(0.2)	0	(0.0)	2	(0.0)
Rash erythematous	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)
Rash pruritic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Scall	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Skin discolouration	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	4	(0.1)	8	(0.1)	1	(0.0)	5	(0.1)
Skin tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Skin induration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Skin burning sensation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Butterfly rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Circumoral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders	0	(0.0)	0	(0.0)	2	(0.3)	18	(2.6)	0	(0.0)	0	(0.0)	8	(0.1)	72	(1.0)	0	(0.0)	0	(0.0)
Arthralgia	0	(0.0)	0	(0.0)	0	(0.0)	12	(1.7)	0	(0.0)	0	(0.0)	2	(0.0)	72	(1.0)	0	(0.0)	0	(0.0)
Back pain	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	2	(0.0)	38	(0.4)	0	(0.0)	0	(0.0)
Bone pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)
Flank pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Groin pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)	0	(0.0)
Muscle weakness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	4	(0.1)	0	(0.0)	1	(0.0)
Myalgia	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)	0	(0.0)
Neck pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	9	(0.1)	0	(0.0)	0	(0.0)
Pain in extremity	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	15	(0.2)	0	(0.0)	0	(0.0)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)	1	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal stiffness	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

Table 19-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

Sample size	Immune abnormality																									
	Unidentified adverse events										Fatal															
	Yes					No					Death					Recovering										
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown	Total							
Number of subjects with ADRs	0	0	0	12	101	0	0	0	703	30	308	2	0	0	0	7707	31	301	2							
Type of ADR	Number of subjects with ADRs (%)										Number of subjects with ADRs (%)															
Head and sensory disorders	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)				
Hemianopia	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)				
Nocutaria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)				
Polakaria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)		
Polyuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)				
Unilateral pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)				
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)				
General disorders and administration site conditions	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	12	(4.3)	12	(4.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)				
Aches	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)		
Chest pain	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	1	(0.0)	0	(0.0)	11	(0.1)	1	(0.0)		
Chills	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)		
Condition aggravated	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)		
Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)		
Facial pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)		
Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	13	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	14	(0.2)	0	(0.0)		
Feeling abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)		
Feeling cold	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)		
Feeling hot	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.1)	0	(0.0)		
Injection site paronychia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Malaise	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	37	(0.5)	1	(0.0)	0	(0.0)	0	(0.0)	40	(0.5)	1	(0.0)		
Muscle	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Oedema peripheral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	2	(0.0)	0	(0.0)		
Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	11	(0.2)	0	(0.0)	0	(0.0)	11	(0.1)	0	(0.0)		
Pryexa	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)		
Swelling	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)		
Swelling face	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)		
Thirst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	6	(0.1)	0	(0.0)		
Achilles pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.1)	9	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)		
Periphereal swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)		
Injected limb mobility decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Vaccination site erythema	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	12	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	13	(0.2)	0	(0.0)		
Vaccination site reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Vaccination site induration	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)		
Vaccination site pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	16	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	16	(0.2)	0	(0.0)		
Vaccination site pruritus	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.4)	36	(5.1)	0	(0.0)	2	(0.0)	181	(2.6)	0	(0.0)	0	(0.0)	5	(0.1)	217	(2.8)	0	(0.0)
Vaccination site discoloration	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	0	(0.0)		
Vaccination site haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Vaccination site discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Vaccination site rash	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Vaccination site bruising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Vaccination site swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	0	(0.0)		
Vaccination site vesicles	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)		
Vaccination site warmth	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.6)	0	(0.0)	0	(0.0)	2	(0.0)	6	(0.1)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)		
Vaccination site exema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)		
Vaccination site mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)		
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	1	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	1	(0.0)	6	(0.1)	0	(0.0)
Blood pressure increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Heart rate	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Heart rate increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oxygen saturation	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)
Interventions and procedural complications	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)
Heart illness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

If multiple events with the same PT occur in the same sub
Note) If the onset date of an ADR was unknown and odds

As of Sep 8, 2025

As of Sep 8, 2025

	Immune abnormality																																																											
	Combined total																																																											
	Yes										No																																																	
	Death					Recovered with sequelae					Not recovered					Recovering					Unknown					Death					Recovered with sequelae					Not recovered					Recovering					Unknown														
	U					U					U					U					U					U					U					U					U					U					U					U				
Sample size	Number of subjects with ADRA (%)																																																											
Type of ADRA	Number of subjects with ADRA (%)																																																											
Infectious and inflammatory	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.1)	0	(0.0)																								
Conjunctivitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Gastroenteritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																						
Gastroenteric viral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Herpes virus infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Herpes zoster	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																								
Pneumia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)																								
Rhinitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)																								
Cytitis bacterial	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Otitis externa	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)																						
Mixed and lymphatic system disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Lymph node pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.1)	0	(0.0)																								
Lymphadenopathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	14	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	15	(0.2)	0	(0.0)																						
Metabolism and nutrition disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)																						
Decomposed adipose	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	23	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	24	(0.3)	0	(0.0)																						
Psychiatric disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Dissective arthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																								
Euphoric mood	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Hallucinations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)																						
Latencies	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																						
Nervous system disorders	0	(0.0)	0	(0.0)	0	(0.0)	38	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	38	(1.3)	0	(0.0)																								
Dizziness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	24	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)	32	(0.4)	0	(0.0)																						
Dizziness postural	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																						
Dyspareunia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)																						
Dyspareunia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Head discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	0	(0.0)																						
Headache	0	(0.0)	0	(0.0)	0	(0.0)	16	(2.3)	237	(33.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	102	(1.5)	2182	(31.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	118	(1.5)	2419	(31.4)	1	(0.0)																						
Hypoaesthesia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)																						
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Movement disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																								
Numbness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)																						
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	9	(0.1)	1	(0.0)																								
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Peripheral nerve palsy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																						
Somnolence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	18	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	18	(0.3)	0	(0.0)																						
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Balance disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	5	(0.1)	0	(0.0)																						
Taste disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Brain fog	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	2	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.0)	2	(0.0)	0	(0.0)																						
Eye disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	13	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	13	(0.2)	0	(0.0)																						
Eye discharge	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Eye inflammation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.0)	0	(0.0)																								
Eye irritation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)																								
Eye pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.1)	0	(0.0)																						
Retinal hemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0</																																															

As of Sep 8, 2025

As of Sep 8, 2025

[illegible]

Table 19-2 Outcome of ADRs in subjects with special va

Subjects included in safety analysis

As of Sep 8, 2025

Sample size	Immune abnormality															
	Combined total															
	Yes								No							
	Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown			Death	Recovered with sequelae	Not recovered	Recovering	Recovered	Unknown		
Number of subjects with ADRs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Type of ADR	Number of subjects with ADRs (%)								Number of subjects with ADRs (%)							
Respiratory disorders	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hematuria	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Necrosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Polakiuria	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Polyuria	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Urinary incontinence	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
General disorders and administration site conditions	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aches	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Chest pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Chills	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Condition aggravated	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Discomfort	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Facial pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fatigue	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feeling abnormal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feeling cold	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Feeling hot	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Injection site paronychia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaise	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Muscle pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Oedema peripheral	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pruritus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swelling face	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Thirst	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Achilles pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Peripheral swelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Injected limb mobility decreased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site erythema	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site reaction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site induration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site pain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site pruritus	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site discoloration	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site haematoma	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site discomfort	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site rash	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site bruising	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site swelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site vesicles	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site warmth	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site exema	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vaccination site mass	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Investigations	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Blood pressure increased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C-reactive protein increased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heart rate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heart rate increased	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Oxygen saturation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hypertension and procedural complications	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heart illness	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

If multiple events with the same PT occur in the same sub
Note) If the onset date of an ADR was unknown and odds

MedDRA v 28.05

Drug Use Investigation on Shingrix for Intramuscular Injection Statistical Analysis Plan

Study Title: Drug Use Investigation on Shingrix for Intramuscular Injection
Protocol No: 212853

Version : 7.0
Date: 12 Aug 2025

Approved by:

PPD



Signature

(Signed)

Approved by:

PPD



Signature

(Signed)

Original is written in Japanese.

Table of Contents

1. Objectives of surveillance	4
2. Software and Dictionaries to be Used	4
2.1. Statistical analysis and tabulation software	4
2.2. Dictionary to be used	4
3. Definition of Terms	4
4. Handling of subjects and data	5
4.1. Number of subjects	5
4.2. Analysis population/sites	5
4.3. Exclusion criteria from analysis	7
4.3.1. Subjects excluded from safety analysis	7
4.3.2. Subjects excluded from efficacy analysis	8
4.3.3. Subjects excluded from other analyses	8
4.4. Handling of missing data	8
4.4.1. Data imputation	8
4.4.2. Missing data of continuous data	8
4.4.3. Categorical data	8
4.4.4. Date variables	8
4.5. End date of administration in continued vaccination	9
4.6. Handling of presence/absence	9
4.7. Calculation of Number of Days and Age	9
4.8. Handling of subject transfer	10
4.9. Adverse reactions/adverse reactions	10
4.9.1. Definition of adverse reactions/adverse reactions	10
4.9.2. Time of onset of adverse reactions	11
4.9.3. Handling of adverse event severity Grade 0	11
4.10. Definition of Safety Specification, Underlying Disease, and Medical History	11
4.10.1. Safety Specification	11
4.10.2. Underlying disease “Renal impairment” and “Hepatic impairment”	11
4.10.3. Herpes zoster	12
4.10.4. Persons Requiring Caution and Immunologic Abnormalities	12
4.11. Special Characteristics of Subjects	12
5. Matters related to statistical processing	13
5.1. Summary statistics	13
5.2. Percentage	13
5.3. Display of results	13

5.4.	Exploratory analysis of influencing factors	14
6.	Primary analysis items	14
6.1.	Subject composition	14
6.1.1.	Subject composition (Figure1.01)	14
6.2.	Subject characteristics and baseline characteristics	15
6.2.1.	Subject composition ratio (Table1.01).....	15
6.2.2.	Characteristics of subjects (Table1.02 to Table1.04)	16
6.2.3.	Characteristics of subjects (presence or absence of subjects requiring caution) (Table1.05).....	18
6.2.4.	Characteristics of subjects (reasons for vaccination) (Table1.06).....	19
6.3.	Safety evaluation	20
6.3.1.	Occurrence of adverse reactions by characteristics of subjects (Table2.01).....	20
6.3.2.	Time to onset of adverse reactions (Table2.02)	21
6.3.3.	Total dose by type of adverse reaction (Table2.03)	22
6.3.4.	Outcome of serious adverse reactions by seriousness (Table2.04 to Table2.05).....	22
6.3.5.	Occurrence of adverse reactions by safety specification (Table2.08 to Table2.09)	23
6.3.6.	Occurrence of adverse reactions in subjects with special characteristics (Table2.12, Table2.13).....	24
6.3.7.	Occurrence of adverse reactions by severity (Table2.23).....	25
6.4.	Efficacy evaluation	25
6.5.	Background of subjects Background of subjects.....	26
6.6.	Exploratory Analysis.....	26
6.6.1.	Monovariate logistic regression analysis (Safety: Table2.14).....	26
6.6.2.	Correlation of each factor (safety: Table2.15)	27
6.6.3.	Multivariate analysis (safety: Table2.16).....	28
6.6.4.	Number of subjects by underlying disease (Table2.17)	28
6.6.5.	Number of subjects by medical history (past) (Table2.18)	29
6.6.6.	Number of subjects by Prior drug (Table2.19)	29
6.6.7.	Number of subjects by concomitant drug (Table2.20).....	30
6.6.8.	Number of subjects by drug category(Table2.21)	30
6.6.9.	Occurrence of adverse reactions by selected factors (Table2.22)	31
6.6.10.	Occurrence of adverse reactions by of underlying disease related to immune abnormality (Table2.24).....	31
6.6.11.	Occurrence of adverse reactions by prior drugs related to immune abnormality (Table2.25)	32
7.	Change History	33
8.	Appendix A Handling of drug category by administration timing	37

1. Objectives of surveillance

To understand the presence or absence of safety problems and questions under the actual use status of Shingrix for Intramuscular Injection (hereinafter referred to as this vaccine).

2. Software and Dictionaries to be Used

2.1. Statistical analysis and tabulation software

	Software and Version
OS	Microsoft Windows 10 Or use the later version.
Statistical analysis software	SAS Ver.9.4 Or use the later version.
Tabulation software	Microsoft Excel 2016 Or use the later version.

2.2. Dictionary to be used

Item	Dictionary name
Name of disease (underlying disease and medical history), name of adverse event/name of adverse reaction	MedDRA/J (* The version of MedDRA to be used will be discussed and determined by the team for each report.)
Name of drug, name of drug component	Iyakuhinmei Data File (IDF) of MT Committee (* In principle, use the latest one.)

3. Definition of Terms

Term	Definition
Date of first vaccination with this vaccine	The date of first vaccination recorded in the "vaccination status with this vaccine" in CRF.
Date of second vaccination with this vaccine	The date of the last vaccination recorded in the "Status of vaccination with this vaccine" section of CRF for subjects who received vaccination twice.
Observation period at the time of the first vaccination	For 30 days from the date of the first vaccination with this vaccine (the date of vaccination will be Day 1)
Observation period at the time of the second vaccination	For 30 days from the date of the second vaccination with this vaccine (the date of vaccination will be Day 1)

Term	Definition												
End date of observation period	The end date of observation period for each vaccination is as follows: First vaccination: Day of the first vaccination with this vaccine +29 days Second vaccination: Day of the second vaccination with this vaccine +29 days However, if the end date of observation period for the first vaccination with this vaccine is after the day of the second vaccination with this vaccine, the day before the day of second vaccination with this vaccine will be regarded as the end date of observation period for the first vaccination with this vaccine. (See examples below.) Example) <table><tr><th></th><th>Date of vaccination with this vaccine</th><th>Date of vaccination with this vaccine + 29</th><th>End date of observation period</th></tr><tr><td>First</td><td>2020/1/1</td><td>2020/1/30</td><td>2020/1/24</td></tr><tr><td>Second</td><td>2020/1/25</td><td>2020/2/23</td><td>2020/2/23</td></tr></table>		Date of vaccination with this vaccine	Date of vaccination with this vaccine + 29	End date of observation period	First	2020/1/1	2020/1/30	2020/1/24	Second	2020/1/25	2020/2/23	2020/2/23
	Date of vaccination with this vaccine	Date of vaccination with this vaccine + 29	End date of observation period										
First	2020/1/1	2020/1/30	2020/1/24										
Second	2020/1/25	2020/2/23	2020/2/23										

4. Handling of subjects and data

4.1. Number of subjects

✧ Number of subjects: Number of subjects meeting the applicable conditions.

4.2. Analysis population/sites

Item	Definition
Enrolled Subjects	Subjects enrolled within the protocol-specified registration period (August 2020 to June 2024) (eligible subjects for enrollment). Subjects with enrollment date were available, and the date was prior to the date of data lock

Item	Definition
Enrolled Site	Investigation Sites for all enrolled subjects (subjects eligible for enrollment). Sites with subjects with enrollment date were available, and the date was prior to the date of data lock. (excluding duplication of site code).
Subjects CRFs collected	All enrolled subjects whose CRFs were collected. Subjects whose CRFs were collected at the above "Sites CRF collected"
Sites where CRF collected	All enrolled sites from which CRFs were collected. sites with subjects for whom the "CRF status" in CRF information of the PMS progress management system is other than "Not obtained," "Request for acquisition," or blank. In the data of PMS progress management system, site with subject with "the date of CRF receipt at head office " and the date is prior to date of data lock.
Subjects with locked CRF	All enrolled subjects whose CRFs were collected and locked.
Sites with locked CRFs	Sites with locked CRFs among sites where CRFs were collected. Sites with subjects whose "CRF status" in CRF information of the PMS progress management system is "fully approved" Sites with a value on the "CRF approval date" and the date on or before the date of data lock
Safety analysis population	In the subjects with locked CRF, subjects who do not meet the safety analysis exclusion criteria (see 4.3.1)
Site with Safety analysis population	Investigation site with subjects with locked CRF who do not fall under the safety analysis exclusion criteria (see 4.3.1).
First vaccination	Subjects who received the first vaccination, in safety analysis population
Second vaccination	Subjects who received the second vaccination, in safety analysis population. Subjects who do not fall under the safety analysis exclusion criteria at second vaccination
Cumulative vaccination	Total number of first and second vaccinations in the safety analysis population Example) Each vaccination is counted as one dose. When one subject receives vaccinations two times, the cumulative number of vaccinated dose is two.

Item	Definition
Second vaccination subjects excluded from safety analysis	Subjects in the safety analysis population who met any of the following: • Unvaccinated with the second vaccination of this vaccine: Subjects in the safety analysis population who did not receive the second vaccination • Other
Subjects in the efficacy analysis population	Not applicable in this investigation

4.3. Exclusion criteria from analysis

4.3.1. Subjects excluded from safety analysis

If reasons for exclusion overlap and need to be prioritized, the reasons for exclusion from safety analysis will be assigned in the following order:

Code	Reason for exclusion from analysis in Safety	Priority Rank	Conditions for exclusion	Logic Judgment
S1	Withdrawal of consent	1	Subjects who withdrew consent after enrollment in this investigation	Yes
S2	Outside of the investigation/enrollment period	2	• The date of the first vaccination with this vaccine or the date of the second vaccination with this vaccine is outside the investigation period • The date of enrollment is outside the enrollment period	Yes
S3	Outside the contract period	3	• The date of first vaccination with this vaccine or the date of last observation is outside the contract period • The date of enrollment is outside the contract period	Yes
S4	Violation in enrollment	4	• Not enrolled within 8 days after the first vaccination with this vaccine (the date of vaccination is defined as Day 1) • Not the first vaccination with this vaccine	Yes No
S5	Not vaccinated	5	Subjects no description of the vaccination status of this vaccine, or the description of the dose is 0 mL	Yes

S6	Unknown adverse event data	6	Presence or absence of adverse event is blank and there is no adverse event data	Yes
S7	Other	7	Exclusions determined by the case review meeting under conditions other than the above.	No

4.3.2. Subjects excluded from efficacy analysis

Not applicable in this investigation.

4.3.3. Subjects excluded from other analyses

Not applicable in this investigation.

4.4. Handling of missing data

4.4.1. Data imputation

No imputation will be performed for missing data unless otherwise specified.

4.4.2. Missing data of continuous data

If there is any missing data in the tabulation of continuous data, it will be excluded from the tabulation. If there are data of continuous at multiple time points, only the missing time point will be excluded. Categorization of continuous data shall be performed in accordance, 4.4.3 Categorical Data should be followed.

4.4.3. Categorical data

- ✧ “Unknown” will be handled without making distinction between missing, unknown, and not recorded.
- ✧ “Unknown” will be included in the denominator of the percentage of proportion.
- ✧ Unknown categories will be excluded when calculating odds ratios.

4.4.4. Date variables

Imputation of date variables will be handled as follows.

< Adverse reactions >

If the date of onset and the date of outcome are missing, they will not be imputed and will be handled as unknown.

< Prior medications/prior therapies/vaccines used (other than this vaccine)/Drugs used/prior therapies (other than drugs) >

Handle as described in Appendix A.

4.5. End date of administration in continued vaccination

Not applicable in this investigation.

4.6. Handling of presence/absence

The presence or absence of adverse reactions will be handled as follows. For other items, the presence or absence will be determined based on the presence or absence of coding or detailed description. If there is coding or detailed description, it will be “present”.

Description in the presence/absence column	Presence/absence of detailed item record	Handling of presence/absence
No	No	“No ”.
	Yes	“Yes ”.
Yes	No	“Unknown ”.
	Yes	“Yes ”.
Unknown/Not specified	No	“Unknown ”.
	Yes	“Yes ”.

4.7. Calculation of Number of Days and Age

✧ Number of days (days)

The number of days from the date of the first vaccination with this vaccine will be calculated as follows when the target date is before and after the date of the first vaccination with this vaccine.

- Date of the first vaccination with this vaccine $\leq$ target date: target date - date of the first vaccination with this vaccine + 1
- Date of the first vaccination with this vaccine $>$ target date: target date - date of the first vaccination with this vaccine

*The number of days (days) of the date of the first vaccination with this vaccine will be indicated as 1 for the date of the first vaccination with this vaccine and -1 for the day before the first vaccination with this vaccine, with 0 not used.

✧ Age

Age data described in CRF will be adopted. However, if no age data is described, the date of first vaccination with this vaccine will be used for calculation.

- Year of birth (June 30 imputed) - Date of first vaccination with this vaccine

4.8. Handling of subject transfer

Not applicable in this investigation.

4.9. Adverse reactions/adverse reactions

4.9.1. Definition of adverse reactions/adverse reactions

Term	Definition
Adverse reactions (AEs)	Events entered in Argus Unless otherwise solicited adverse reactions that occur during the observation period will be included in the tabulation. The period between the day after the end date of the observation period for the first vaccination with this vaccine and the day before the date of the second vaccination with this vaccine will be out of the observation period and excluded from the tabulation. However, adverse reactions with unknown onset date will be included in the tabulation. The adverse event that occurred during the observation period at the first vaccination will be counted as the first adverse event, and the adverse event that occurred during the observation period at the second vaccination will be counted as the second adverse event.
Adverse reactions	Adverse reactions other than "Not related" or "Not related" for "Causality as determined" and "Causality as reported"
Solicited AEs	The following adverse reactions that occurred for 7 days after vaccination with this vaccine (from the date of vaccination to Day 7) Local AEs: injection site pain, injection site redness, injection site swelling Systemic AEs: myalgia, fatigue, headache, chills, fever, gastrointestinal symptoms (nausea, vomiting, diarrhea, abdominal pain)
Unsolicited AEs (Other AEs)	AEs other than solicited AEs that occurred within 30 days (Day 1 of vaccination up to Day 30) Includes solicited AEs (local and systemic AEs) described above that occurred beyond 7 days after vaccination
Serious AEs (Adverse Reactions)	Serious AEs (Adverse Reactions)
Severity	Severity of AEs (Adverse Reactions) defined in the guidance
Death related to AEs	Adverse reactions for which the "outcome of adverse event" is "fatal"

4.9.2. Time of onset of adverse reactions

Which number of vaccinations associated with an adverse event will be calculated based on the date of onset of the adverse event and the date of vaccination.

Events occurring at the time of first vaccination: Date of first vaccination $\leq$ date of onset of adverse event $\leq$ date of first vaccination with this vaccine + 29

Events occurring at the time of second vaccination: Date of second vaccination with this vaccine $\leq$ date of onset of adverse event $\leq$ date of second vaccination with this vaccine + 29

If the date of onset of an adverse event is unknown, it will be handled as an event occurring at the time of first vaccination when tabulating adverse reactions. If specified/unspecified cannot be distinguished, only the total will be counted when tabulating adverse reactions.

4.9.3. Handling of adverse event severity Grade 0

Adverse reactions will be tabulated using Argus data. However, since there is no 0 in the Argus grade list, if the description of severity in CRF is “unknown”, “not selected”, or “Grade 0”, it will be entered in Argus and tabulated according to the handling in the table below.

Description of severity in CRF	Argus Entry Handling	Aggregation Handling
Unknown	Enter "Unknown"	Grade Unknown
Not selected	Enter "Unknown"	Grade Unknown
Grade 0	Enter "Blank"	Grade 0

4.10. Definition of Safety Specification, Underlying Disease, and Medical History**4.10.1. Safety Specification**

The following items will be the safety specification in this investigation.

For the definitions, refer to the “Plan for assessment of accumulated adverse reactions to Shingrix for intramuscular injection”.

- Shock, anaphylaxis
- Potentially immune-mediated diseases (pIMD)

4.10.2. Underlying disease “Renal impairment” and “Hepatic impairment”

CRF [Characteristics of subjects] Underlying disease is classified according to the following definitions or dictionary codes in the item of “Underlying disease.”

Classification of underlying disease	Definition	Dictionary Code
Renal impairment	Nephropathy (HLGT)	MedDRA/J HLGT:10029149
	Renal disorder (excl nephropathy) (HLGT)	MedDRA/J HLGT:10038430
	Acute Renal failure (SMQ, broad/narrow)	20000003 (broad/narrow)
Hepatic impairment	PTs included in SMQ level 1 "Liver disorders" and excluding PTs included in SMQ level 3 "Liver related coagulation and bleeding disorders"	SMQ level 1 "Hepatic disorders": (20000006,20000007,)20000008,20000009,20000010,20000011,20000012,20000013,20000014,(20000015,)20000016,20000017,20000018,20000208,20000209 SMQ level 3 "Hepatic related coagulation and bleeding disorders": 20000015

4.10.3. Herpes zoster

History of herpes zoster is as follows.

Definition	Subjects with herpes zoster "present" and subjects with "herpes zoster" in medical history will be tabulated as "present" with a history of herpes zoster.
MedDRA	= > PTs including "herpes zoster" (English name: Herpes Zoster, PT Code: 10019974)

4.10.4. Persons Requiring Caution and Immunologic Abnormalities

In this investigation, the presence/absence of persons requiring caution and the presence/absence of immunologic abnormalities will be tabulated. For the definitions, see the appendix (Definitions for MedDRA extraction the persons requiring caution and immunologic abnormalities in the drug use investigation of Shingrix).

4.11. Special Characteristics of Subjects

Term	Definition
Renal Impairment	Subjects with underlying disease of renal impairment
Hepatic Impairment	Subjects with underlying disease of hepatic dysfunction

Term	Definition
Pediatrics	Subjects aged < 15 years
Geriatric	Subjects aged ≥ 65 years
Pregnant and parturient women	Subjects with presence of pregnancy
Immune abnormality	Subjects with immune abnormality due to underlying disease, prior drugs, or prior therapies

5. Matters related to statistical processing

5.1. Summary statistics

Number of subjects, mean, standard deviation, minimum, 25th percentile, median, 75th percentile, and maximum.

5.2. Percentage

Percentage will be calculated using the following formula.

$$\diamond \text{ Percentage (\%)} = (\text{number of subjects/number of subjects analyzed}) \times 100$$

5.3. Display of results

Tabulation results will be presented as follows.

Category	Display digits
Composition ratio, proportion, Confidence interval of proportion	Round the second decimal place and display to the first decimal place.
Number of subjects	Expressed as an integer.
Mean, standard deviation, 25th percentile, median, 75th percentile, confidence interval of mean	Round off the second digit below the number of digits to be displayed * in the source data and display to the first digit below the number of digits to be displayed.
Minimum, maximum	Round off the first digit below the number of digits to be displayed * in the source data and display to the same digit as the number of digits to be displayed.
Odds ratio, odds ratio Confidence interval, correlation coefficient	Round and display to 3 decimal places.

*If there are multiple digits in the source data, use the maximum number of digits as the reference.

5.4. Exploratory analysis of influencing factors

- ✧ Subjects classified as unknown will be excluded from the calculation of odds ratio.
- ✧ For overlapping tabulation items, odds ratio will not be calculated.
- ✧ Logistic regression analysis will be used to estimate the odds ratio. The odds ratio in each category will be calculated based on “*” in the criterion column. The following criteria will be used to identify factors that have an impact, and any of the following factors will be judged to be signals.
 1. Odds ratio: > 2 or < 0.5
 2. Asymptotic 95% confidence interval: Does not exceed 1

6. Primary analysis items

6.1. Subject composition

6.1.1. Subject composition (Figure1.01)

Analysis Safety analysis population
population:

Analysis details: The following number of subjects, number of subjects excluded, and reasons for exclusion are shown using a flow chart.

If there are multiple reasons for exclusion in the same subject, they will be summarized by the item of higher priority.

The number of sites will be tabulated by site without considering clinical departments.

- Enrolled sites
- Enrolled subjects
- Subject CRF not collected
- Sites where CRF collected
- Subjects CRFs collected
- Subjects CRF not locked
- Sites with locked CRFs
- Subjects with locked CRF
- Subjects excluded from safety analysis population
- Site with Safety analysis population
- Subjects in Safety analysis population

- Number of doses included in safety analysis population (first, second, cumulative dose)

- Number of subjects excluded from second vaccination safety analysis population

Output form: Figure 1.01: Subject composition

6.2. Subject characteristics and baseline characteristics

6.2.1. Subject composition ratio (Table1.01)

Analysis Safety analysis population

population:

Analysis details: The number of subjects, composition ratio (%), and summary statistics will be calculated for each analysis population by baseline characteristics.

Unless otherwise specified, the denominator of the composition ratio (%) is the total of each analysis population. See the output plan for details.

The 25th and 75th percentiles of summary statistics will not be calculated.

Baseline

characteristics:

- Sex: male, female
- Pregnancy status [females only]: no, yes
- Age 1 [years]: < 15, 15 ≤ to < 50, 50 ≤ to < 65, 65 ≤ to < 75, 75 ≤ and summary statistics
- Age 2 [years]: < 65, 65 ≤ , unknown
- Age 3 [years]: < 18, 18 ≤ , unknown
- History of vaccination with herpes zoster vaccine other than this vaccine: No, Yes, unknown
- History of herpes zoster: No, Yes, Unknown
- Classification of individuals requiring caution for vaccination: No, Yes
- Immune abnormality: No, Yes
- Underlying disease (underlying disease related to immune abnormality): No, Yes
- Prior medications (drugs that may affect immunity): No, Yes
- Prior therapies (therapies that may affect immunity): No, Yes
- Underlying disease *: No, Yes
- Underlying disease (renal disease): No, Yes
- Underlying disease (hepatic disease): No, Yes
- Underlying disease (other): No, Yes
- Medical history: No, Yes
- Vaccines used during the first observation period (vaccines other than this vaccine): No, Yes
- Vaccines used during the second observation period (vaccines other than this

vaccine): No, Yes

- Vaccines concomitantly administered with the first vaccination of this vaccine: No,

Yes

- Vaccines concomitantly administered with the second vaccination of this vaccine:

No, Yes

- Concomitant medicine used: No, Yes

- Operated therapy (other than medication): No, Yes

*“Underlying diseases” include Immune abnormality related underlying diseases and underlying diseases (renal disease, hepatic disease, and others)

Output form: Table 1.01.1: Subject Composition

6.2.2. Characteristics of subjects (Table1.02 to Table1.04)

Analysis Safety analysis population

population: Subjects who received the first vaccination among the safety analysis population

Subjects who received the second vaccination among the safety analysis population

Cumulative number of vaccinations among the safety analysis population

Analysis The number of subjects, composition ratio, number of subjects with adverse reactions,
details: and proportion of adverse reactions will be calculated for each analysis population for each vaccinee background item.

The denominator of proportions will be the number of subjects in each analysis population for composition ratio and the number of subjects for each item for proportion of adverse reactions.

The 25th and 75th percentiles of summary statistics will not be calculated.

The vaccination status is defined as follows:

Item	Definition
vaccination interval [days]	Calculate using the following formula for subjects who received 2 doses of this vaccine. Date of second vaccination with this vaccine – Date of first vaccination with this vaccine – 1
Simultaneous vaccination	Vaccines used for which the date of vaccination with this vaccine (first and second vaccinations) and the date of vaccination with the vaccine used (other than this vaccine) are the same. However, if the date of vaccination is an incomplete date, it will be excluded.

Subjects	< Table1.02.1 >
Background variables:	Safety analysis population • Number of vaccinated subjects • Second vaccination: No, Yes • Reasons for not receiving the second vaccination: occurrence of adverse event, pregnancy, vaccination at another hospital, vaccination with another drug, no visit after the day of first vaccination, no visit in the middle, convenience of the vaccinated subject other than the above, decision of the physician other than the above, unknown • vaccination interval of this vaccine[days]: < 27, 27 ≤ to < 55, 55 ≤ to < 83, 83 ≤ to < 111, 111 ≤ to < 139, 139 ≤ to < 167, 167 ≤ to < 185, 185 ≤ , no second vaccination, and summary statistics < Table1.02.2 > Tabulation by each vaccination in the safety analysis population • Body temperature [°C] before vaccination of this vaccine: < 37.5, 37.5 ≤ and summary statistics • Dose volume [mL]: < 0.5, 0.5, 0.5 < and summary statistics • Vaccination site: Upper arm (right, left), others (right, left) • Route of vaccination: Intramuscular, others • Symptoms immediately before vaccination (e.g., poor physical condition on the day): No, Yes < Table1.03 > Safety analysis population • Prior therapies (therapies that may affect immunity): Radiotherapy, anticoagulation therapy, surgery/others • Therapies performed (other than drugs): Radiotherapy, anticoagulation therapy, surgery/others < Table1.04 > Safety analysis population (first vaccination, second vaccination) • Vaccines other than this vaccine: The number of subjects and the proportion of use will be calculated for each vaccine name (general name), and output will be done in the order of vaccines with the largest number of subjects included in safety analysis population or, in the case of drugs with the same number of subjects, in the order of drug codes.

*Drug names (general names) with a 7-digit drug code will be used. However, if the

drug code is less than 7 digits and for a unique code, the entered drug code and applicable drug name will be used as they are.

The proportion of subjects with adverse reactions will be tabulated using the number of subjects treated with each vaccine as the denominator.

- Concomitant vaccines used during the observation period
- Simultaneous vaccination

Output form:

Table 1.02.1: Vaccination status

Table 1.02.2: Vaccination status (first vaccination)

Table 1.02.3: Vaccination status (second vaccination)

Table 1.02.4: Vaccination status (cumulative dose)

Table 1.03: Prior and concomitant therapies
(The proportion of adverse reactions is also shown.)

Table 1.04.1: Concomitant vaccines other than this vaccine: first vaccination
(The proportion of adverse reactions is also shown.)

Table 1.04.2: Concomitant vaccine other than this vaccine: second vaccination
(The proportion of adverse reactions is also shown.)

6.2.3. Characteristics of subjects (presence or absence of subjects requiring caution) (Table1.05)

Analysis population:	Safety analysis population
Analysis details:	The number of subjects for which "Yes" is selected for "Applicability to individuals requiring caution to administer" in CRF [Characteristics of subjects] and the number of subjects judged to be applicable to individuals requiring caution to administer (see 4.10.4) according to the definitions specified in the attachment (Definitions at the Time of MedDRA Extraction of Individuals Requiring Caution to Administer Dose, Immunologic Abnormalities, etc. in the Drug Use Investigation of Shingrix) will be calculated. The number of subjects, composition ratio, number of subjects with adverse reactions, and proportion of adverse reactions will be calculated for each characteristics of subjects. The denominator of the proportions will be the number of subjects in the safety analysis population for the composition ratio and the number of subjects per item for the proportion of adverse reactions.

Subjects	• Physician's judgment: No, Yes
Background variables:	• Logic judgment: No, Yes
Output form:	Table 1.05: Characteristics of subjects (presence or absence of subjects requiring caution)

6.2.4. Characteristics of subjects (reasons for vaccination) (Table1.06)

Analysis population:	Safety analysis population
Analysis details:	The number of subjects selected for each item of "Reason for vaccination" in CRF [Characteristics of subjects] will be calculated (multiple selection allowed). Subjects not selected for all items will be tabulated as "Not selected (before expansion of indications)." The number of subjects, composition ratio, number of subjects with adverse reactions, and proportion of adverse reactions will be calculated for each characteristics of subject. The denominator will be the number of subjects in the safety analysis population for the composition ratio and the number of subjects per item for the proportion of adverse reactions.
Subjects	♦ Age at the time of first vaccination with this vaccine (≥ 50 years)
Background characteristics:	♦ Immunodeficiency due to disease or treatment ♦ immune compromise due to disease or treatment ♦ Immune function may be compromised due to disease or treatment ♦ Other than the above, the physician judges that vaccination with this vaccine is necessary ♦ Not selected (before the expansion of indications)
Output form:	Table 1.06: Characteristics of subjects (reason for vaccination)

6.3. Safety evaluation**6.3.1. Occurrence of adverse reactions by characteristics of subjects (Table2.01)**

Analysis	Safety analysis population
population:	Subjects in the safety analysis population who received the first vaccination Subjects who received the second vaccination among the safety analysis population Total number of subjects who received the second vaccination among the safety analysis population Subjects for whom presence of immune abnormality was selected among the safety analysis population *
Analysis details:	For each background item of subjects, the number of subjects, the number of subjects with solicited adverse reactions, unsolicited adverse reactions, and the combined number of subjects with adverse reactions and the proportion of adverse reactions will be calculated for each analysis population. The denominator of the proportion of adverse reactions will be the number of subjects with each background item. Adverse reactions to be tabulated in each population are as follows. • Safety analysis population: Adverse reactions during the observation period by subject • First vaccination subjects: Adverse reactions during the observation period after the first vaccination • Second vaccination subjects: Adverse reactions during the observation period after the second vaccination • Cumulative dose: Adverse reactions during the observation period after both doses
Subjects	Same variables as “Subject composition (Table1.01)”
Background variables:	
Output	Table2.01.1: Occurrence of Adverse Reactions
variables:	Table2.01.2: Occurrence of Adverse Reactions (First vaccination) Table2.01.3: Occurrence of Adverse Reactions (Second vaccination) Table2.01.4: Occurrence of Adverse Reactions (Cumulative Doses) Table2.01.5: Occurrence of Adverse Reactions (Immunologic Abnormalities) *

*Tabulation for publication (Refer to the output plan in the table of contents)

6.3.2. Time to onset of adverse reactions (Table2.02)

Analysis	Safety analysis population
subjects:	Subjects who received the first vaccination in the safety analysis population Subjects who received the second vaccination in the safety analysis population Cumulative dose of vaccinated subjects in the safety analysis population
Analysis details:	Number of subjects and proportions will be tabulated by SOC and PT by category of days to onset of adverse reactions for each PT, solicited adverse reactions, unsolicited adverse reactions, and in total. Proportions of adverse reactions and cumulative proportions of adverse reactions will be tabulated for each analysis population. Proportions will be calculated by number of days using subjects excluding overlapping adverse reactions. Cumulative proportions will be calculated by number of days using the cumulative number of days for each subject. However, each subject is counted only for the number of days of first onset of adverse reaction by PT. "Unknown" days in the same subject are counted preferentially. Output should be in the descending order of the number of subjects in SOC in the Total column, in the order of international agreement in SOC, in the descending order of the number of subjects in PT, and in the order of PT code. The number of days of onset is calculated as follows. Date of onset - date of each vaccination + 1 The tabulation by each vaccination will be calculated from the date of each vaccination, and the tabulation in the safety analysis population will be calculated from the date of first vaccination with this vaccine. *SOC and PT will be tabulated by SOC and PT of initial onset, respectively. However, analysis for cumulative dose, each event in both vaccinations will be counted in SOC and PT without excluding the initial onset of the same case in first and second vaccination. • Solicited adverse reactions: 1, 2, 3, 4, 5, 6, 7 days • Unsolicited adverse reactions: ≤ 7 days, $7 < \text{to} \leq 15$ days, $15 < \text{to} \leq 30$ days, unknown • Combined: ≤ 7 days, $7 < \text{to} \leq 15$ days, $15 < \text{to} \leq 30$ days, unknown
Output form:	Table2.02.1: Time to onset of adverse reactions * Table2.02.2: Time to onset of adverse reactions (first vaccination) Table2.02.3: Time to onset of adverse reactions (second vaccination) Table2.02.4: Time to onset of adverse reactions (cumulative dose) *

*Output as needed

6.3.3. Total dose by type of adverse reaction (Table2.03)

It will not be prepared or output in this investigation.

6.3.4. Outcome of serious adverse reactions by seriousness (Table2.04 to Table2.05)

Analysis population:	Safety analysis population Subjects who received the first vaccination in the safety analysis population Subjects who received the second vaccination in the safety analysis population Cumulative dose in the safety analysis population Subjects for whom presence of immune abnormality was selected in the safety analysis population *
Analysis details:	The number of subjects and proportion of adverse reactions by solicited adverse reactions, unsolicited adverse reactions, and total (total number/serious) will be tabulated for each analysis population by SOC and PT. The output order will be in the descending order of the number of subjects with SOC, the order of international consensus for SOC, the descending order of the number of subjects with PT, and the order of PT code in the number of subjects in “Total”. In addition, the number of subjects with adverse reactions and the proportion of adverse reactions will be tabulated by outcome of adverse reaction. The denominator will be the number of subjects in each analysis population. *In the tabulation by outcome, if there is a same subject with the same SOC or PT, it will be adopted in the following order of priority and tabulated. Serious > Non-serious > Death > Sequelae > Not recovered > Recovering/resolving > Recovered/resolved > Unknown However, analysis for cumulative dose, each event in both vaccinations will be counted in SOC and PT without excluding the initial onset of the same case in first and second vaccination.
Output form:	Table2.4.1: Outcome of adverse reactions by seriousness Table2.4.2: Outcome of adverse reactions by seriousness (first vaccination) Table2.4.3: Outcome of adverse reactions by seriousness (second vaccination) Table2.4.4: Outcome of adverse reactions by seriousness (cumulative vaccination) Table2.4.5: Outcome of adverse reactions by seriousness (immune abnormality) * Table2.5.1: Outcome of adverse reactions by seriousness Table2.5.2: Outcome of adverse reactions by seriousness (cumulative vaccination) *Tabulation for publication (see the output plan in table of contents)

6.3.5. Occurrence of adverse reactions by safety specification (Table2.08 to Table2.09)

Analysis	Safety analysis population
population:	Subjects who received the first vaccination in the safety analysis population Subjects who received the second vaccination in the safety analysis population
Analysis details:	The proportion of adverse reactions will be tabulated by seriousness (total number/serious) and PT for each safety specification item for each analysis population. The output order will be in the descending order of the number of subjects with SOC in the total number sequence, in the order of international consensus for SOC, in the descending order of the number of subjects with PT, and in the order of PT code. (Table 2.08) In addition, the number of subjects with adverse reactions and the proportion of adverse reactions will be tabulated by outcome for each safety specification item. (Table 2.09) The denominator is the number of subjects in each analysis population. *If there is a same subject with the same SOC or PT in the tabulation by outcome, it will be adopted in the following order of priority and tabulated. Death > sequelae > not recovered > recovering > recovered > unknown
Safety specification:	See “4.10 Definitions of Safety Specification, Underlying Disease, and Medical History.”
Output form:	Occurrence of Adverse Reactions by Safety Specification Table2.08.1: Occurrence of Adverse Reactions by Safety Specification (Shock, anaphylaxis) Table2.08.2: Occurrence of Adverse Reactions by Safety Specification (Shock, anaphylaxis) (first vaccination) * Table2.08.3: Occurrence of Adverse Reactions by Safety Specification (Shock, anaphylaxis) (second vaccination) * Table2.08.4: Occurrence of Adverse Reactions by Safety Specification (pIMD) Table2.08.5: Occurrence of Adverse Reactions by Safety Specification (pIMD) (first vaccination) * Table2.08.6: Occurrence of Adverse Reactions by Safety Specification (pIMD) (second vaccination) * Outcome of adverse reactions by safety specification Table2.09.01: Outcome of adverse reactions by safety specification (Shock, anaphylaxis) Table2.09.04: Outcome of adverse reactions by safety specification (pIMD)

*Output as necessary

6.3.6. Occurrence of adverse reactions in subjects with special characteristics (Table2.12, Table2.13)

Analysis	Safety analysis population
subjects:	Cumulative dose in the safety analysis population
Analysis details:	For subjects with special characteristics of subjects, the proportions of solicited adverse reactions, non-solicited adverse reactions, and total number of adverse reactions (number of subjects/seriousness) by PT will be tabulated for each analysis population. The output is listed in descending order of the number of subjects by SOC in the total number sequence, internationally agreed order of SOC, number of subjects by PT, and PT code. In addition, the number of subjects with adverse reactions and the proportion of adverse reactions will be tabulated by outcome of adverse reaction. The denominator is the number of subjects for each analysis population by characteristics of subjects. *If there is a subject with adverse reactions of the same SOC or PT, it will be adopted in the following order of priority and tabulated. Death > Sequelae > Not recovered > Recovering > Recovered > Unknown
Special characteristics:	4.11 Subjects with special and vaccinee characteristics
Output form:	Occurrence status of adverse reactions in subjects with special background/Outcome of adverse reactions in subjects with special background Table2.12.1/Table2.13.1: Occurrence of Adverse Reactions in Renal impairment Table2.12.2/Table2.13.2: Occurrence of Adverse Reactions in Renal impairment (cumulative dose) * Table2.12.3/Table2.13.3: Occurrence of Adverse Reactions in Hepatic impairment Table2.12.4/Table2.13.4: Occurrence of Adverse Reactions in Hepatic impairment (cumulative dose) * Table2.12.5/Table2.13.5: Occurrence of Adverse Reactions in Pediatric Table2.12.6/Table2.13.6: Occurrence of Adverse Reactions in Pediatric (cumulative dose) * Table2.12.7/Table2.13.7: Occurrence of Adverse Reactions in Elderly Table2.12.8/Table2.13.8: Occurrence of Adverse Reactions in Elderly (cumulative dose) * Table2.12.9/Table2.13.9: Occurrence of Adverse Reactions in Pregnant and parturient

women

Table2.12.10/Table2.13.10: Occurrence of Adverse Reactions in Pregnant and parturient women (cumulative dose) *

Table2.12.11/Table2.13.11: Occurrence of Adverse Reactions in Immune abnormality

Table2.12.12/Table2.13.12: Occurrence of Adverse Reactions in Immune abnormality (cumulative dose) *

*Output as necessary

6.3.7. Occurrence of adverse reactions by severity (Table2.23)

Analysis	Safety analysis population
population:	Subjects who received the first vaccination in the safety analysis population Subjects who received the second vaccination in the safety analysis population Cumulative number of vaccinations in the safety analysis population
Analysis details:	The proportion of adverse reactions by severity (0, 1, 2, 3) of solicited adverse reactions, unsolicited adverse reactions, and combined total will be tabulated for each SOC and PT for each analysis population. Data will be output in the order of international consensus of SOC, in descending order of the number of PTs, and in the order of PT code. The denominator is the number of subjects in each analysis population. *If there is the same SOC or PT in the same subject, it will be adopted in the following order of priority and tabulated. 3 > 2 > 1 > 0 > unknown
Output form:	Table2.23.1: Occurrence of adverse reactions by Severity Table2.23.2: Occurrence of adverse reactions by Severity (First vaccination) Table2.23.3: Occurrence of adverse reactions by Severity (Second vaccination) Table2.23.4: Occurrence of adverse reactions by Severity (Cumulative dose) *

*Output as necessary

6.4. Efficacy evaluation

Not applicable in this investigation.

6.5. Background of subjects Background of subjects

- ✧ List for consideration of inclusion/exclusion (Listing1)
- ✧ List of adverse reactions (Listing2)
- ✧ List of case report forms and subjects (Listing3)
- ✧ List of serious adverse reactions (Listing4)
- ✧ List of adverse reactions of safety specification (all subjects) (Listing5.1)
- ✧ List of adverse reactions of safety specification (Serious Subjects) (Listing5.2) *
- ✧ List of deaths (Listing6)
- ✧ List of adverse reactions in subjects excluded from safety analysis population(Listing7)
- ✧ List of administration status of this vaccine (Listing8)
- ✧ List of administration status of drugs other than this vaccine (Listing9)
- ✧ Occurrence of adverse drug reactions and infections in post-marketing Surveillance. (Attached Form 2, Attached Form 15)
- ✧ Occurrence of adverse drug reactions and infections in the additional pharmacovigilance plan (Attached Form 12, Attached Form 15)
- ✧ List of Subject summaries (Attached Form 16)

*Output as necessary

6.6. Exploratory Analysis

Factors affecting the presence/absence of adverse reactions (vaccinee background/baseline characteristics) will be explored using statistical models such as logistic regression.

6.6.1. Monovariate logistic regression analysis (Safety: Table2.14)

Analysis population:	Safety analysis population
Analysis details:	The number of subjects, number of subjects with adverse reactions, and proportion of adverse reactions will be calculated for each factor. In addition, univariate analysis using a logistic regression model will be performed. The unadjusted odds ratio in each category will be calculated with reference to “*” in the criterion column. If phrase of “there is no maximum likelihood estimate ” or “ the validity of model fitting is questionable ” is output on the SAS log, the relevant variable is shown with a diagonal line since the model is not fit.

Exploratory variables:	• Sex • Age 1 (years) • Age 2 (years) • History of herpes zoster vaccination other than this vaccine • History of herpes zoster • Applicable to persons requiring caution for vaccination • Immune abnormality • Underlying disease related to immune abnormality • Prior drugs (drugs that may affect immunity) • Prior therapies (therapies that may affect immunity) • Underlying disease • Underlying disease (renal disease) • Underlying disease (liver disease) • Underlying disease (other) • Medical history (past)
Output form:	Table2.14. Monovariate logistic regression analysis
Sample code:	<pre>proc logistic data = TargDs ; class var1/param = ref ; model TargVar(event = '1') = var1 ; /* Designate objective variables for TargVar and explanatory variables for var1 */ link = logit clodds = wald alpha = .05 ods output OddsRatios = out ; run ;</pre>

6.6.2. Correlation of each factor (safety: Table2.15)

Analysis population:	Safety analysis population
Analysis details:	For exploratory variables, Spearman's rank correlation coefficients among categorical variables will be calculated by the bracketed cross-tabulation. The exploratory variables will be used as the baseline characteristics of subjects in "6.6.1. Logistic regression analysis by univariate analysis (Table 2.14)."
Output form:	Table2.15. Correlation of each factor

Sample code: proc corr data = TargDs outs = out spearman ;
 var var1 var2 ; /* For var1 and var2, specify the variable for which the correlation
 coefficient is to be calculated */
 run ;
 *For the results, refer to _TYPE_.

6.6.3. Multivariate analysis (safety: Table2.16)

Analysis population:	Safety analysis population
Analysis details:	The number of subjects, number of subjects with adverse reactions, and proportion of adverse reactions will be calculated for each factor. A multivariate analysis using a logistic regression model will be performed, excluding factors with large bias, many missing values, or factors strongly related to each factor in their correlation. The adjusted odds ratio of each category and its 95% confidence interval will be calculated with reference to “*” in the criterion column. Since the model does not fit in a form on the SAS log in which a phrase such as “there is no maximum likelihood estimate ” or “ the validity of model fitting is questionable ” is output, it is shown with a diagonal line.
Exploratory variables:	Determined based on “6.6.1. Logistic regression analysis by univariate analysis (safety: Table2.14)” and “6.6.2 Correlation of factors (safety: Table 2.15) ”. If the relationship between factors is high ($R \geq 0.7$ or $R \leq -0.7$) and there are 10% or more missing values, consider excluding them from the exploratory variables.
Output form:	Table2.16. Multivariate analysis

6.6.4. Number of subjects by underlying disease (Table2.17)

Analysis population:	Safety analysis population
Analysis details:	The number of subjects with underlying disease (number of subjects with underlying disease) and the proportion of underlying disease will be calculated for each SOC and PT by category of underlying disease (including underlying disease related to immune abnormality). Table will be output in the descending order of the number of subjects in the safety

SOC, in the order of international agreement in the SOC, in the descending order of the number of subjects in the PT, and in the order of PT code.

The denominator of the proportion of underlying disease is the number of subjects included in the safety analysis population. The number of subjects with adverse reactions and the proportion of adverse reactions will be calculated.

The denominator of the proportion of adverse reactions is the number of subjects with underlying disease by SOC and PT.

Underlying disease	For renal disease and hepatic disease, see 4.11 Special Characteristics of Subjects.
Output form:	Table2.17.1: Underlying disease Table2.17.2: Underlying disease (renal impairment) Table2.17.3: Underlying disease (liver impairment)

6.6.5. Number of subjects by medical history (past) (Table2.18)

Analysis population:	Safety analysis population
Analysis details:	The number and proportion of subjects with past medical history will be calculated by each SOC and PT. Data will be output in the descending order of the number of subjects in the safety SOC, in the order of international agreement in the SOC, in the descending order of the number of subjects in the PT, and in the order of PT code. The denominator of the proportion is the number of subjects included in safety analysis population. The number and proportion of subjects with adverse reactions will be calculated. The denominator of the proportion of adverse reactions is the number of subjects with medical history by SOC and PT.
Output form:	Table 2.18: Number of subjects by medical history symptom

6.6.6. Number of subjects by Prior drug (Table2.19)

Analysis population:	Safety analysis population
Analysis details:	The number of target subjects (number of subjects using the drug) and the proportion of use are calculated by drug category, drug name, and drug code for the drugs entered in the category of previous use, and output is performed in the order of the drug

category with the largest number of subjects in the safety analysis population, in the descending order of the number of subjects in the safety analysis population, and in the order of the drug code.

*A 3-digit and 7-digit drug code should be used. However, if the drug code is less than 7 digits or a unique code, the entered drug code and drug name should be used as they are.

The number of subjects with adverse reactions and the proportion of adverse reactions will be calculated.

The denominator of the proportion of use is the number of safety analysis population. The denominator of the each proportion of adverse reactions is the number of subjects per drug.

Output form: Table 2.19: Number of subjects by prior drug

6.6.7. Number of subjects by concomitant drug (Table2.20)

Analysis population: Safety analysis population

Analysis details: The number of subjects included (number of subjects treated with drugs) and the proportion of use will be calculated for each drug code, drug category, and drug name, and output will be done in the order of drug category with the largest number of subjects included in safety analysis, in the descending order of the number of subjects included in safety analysis, and in the order of drug code.

*A 3-digit or 7-digit drug code will be used. However, if the drug code is less than 7 digits or a unique code, the entered drug code and drug name will be used as they are. For the safety analysis population, the number of subjects with adverse reactions and the proportion of adverse reactions will be calculated.

The denominator for the proportion of use is the number of subjects in the safety analysis population.

The denominator for the proportion of adverse reactions is the number of subjects by drug.

Output form: Table 2.20: Number of subjects by concomitant drug

6.6.8. Number of subjects by drug category(Table2.21)

This ledger will not be prepared or output after the seventh Periodic Safety Report.

Analysis population:	Safety analysis population
Analysis details:	For prior drugs and drugs used, the number of subjects (number of subjects using drugs) and the proportion of use are calculated for each drug category, drug name, and route of administration, and output is done in the descending order of the number of subjects in the safety analysis population and the drug code. For the safety analysis population, the number of subjects with adverse reactions and the proportion of adverse reactions are calculated. The denominator for the proportion of use is the number of subjects in the analysis population. The denominator for the proportion of adverse reactions is the number of subjects per drug.
Output form:	Table 2.21: Number of subjects by drug category

6.6.9. Occurrence of adverse reactions by selected factors (Table2.22)

Analysis subjects:	Safety analysis population
Analysis details:	If unadjusted or adjusted odds ratios and their 95% confidence intervals shown in “6.6.1 Monovariate logistic regression analysis (Safety: Table 2.14)” or “6.6.3 Multivariate analysis (Safety: Table 2.16)” meet the criteria shown in “5.4. Exploratory analysis of influential factors”, summary tables of adverse reactions for the factor will be performed. (Refer to 6.3.6 Occurrence of adverse reactions in subject with special background.)
Output form:	Table 2.22.x: Occurrence of adverse reactions by selected factors

6.6.10. Occurrence of adverse reactions by of underlying disease related to immune abnormality (Table2.24)

Analysis population:	Safety analysis population
Analysis details:	The number and proportion of subjects will be calculated for each SOC and PT for category of underlying disease related to immune abnormality. Table will be output in the descending order of the number of subjects in the safety SOC, in the order of international agreement in the SOC, in the descending order of the number of subjects in the PT, and in the order of PT code.

The denominator of the proportion of underlying disease is the number of subjects included in the safety analysis population. The number of subjects with adverse reactions and the proportion of adverse reactions will be calculated for solicited adverse reactions, unsolicited adverse reactions, and total (solicited adverse reactions and unsolicited adverse reactions).

The denominator of the proportion of adverse reactions is the number of subjects with underlying disease by SOC and PT.

Output form: Table 2.24: Occurrence of adverse reactions by of underlying disease related to immune abnormality

*Tabulation for publication (see the output plan in table of contents)

6.6.11. Occurrence of adverse reactions by prior drugs related to immune abnormality (Table2.25)

Analysis Safety analysis population

subjects:

Analysis The number and proportion of subjects will be calculated for each drug code, drug details: category, and drug name for the drugs for prior drugs, and output will be done in the order of drug category with the largest number of subjects included in safety analysis, in the descending order of the number of subjects included in safety analysis, and in the order of drug code.

*Drug codes will be 3-digit and 7-digit. However, if the drug code is less than 7-digit, the entered drug code and drug name will be used as they are.

The number and proportion of subjects with adverse reactions will be calculated for solicited adverse reactions, unsolicited adverse reactions, and total (solicited adverse reactions and unsolicited adverse reactions).

The denominator for the proportion of use is the number of subjects included in safety analysis population.

The denominator for the proportion of adverse reactions is the number of subjects per drug.

Output form: Table 2.25: 6.6.11. Occurrence of adverse reactions by prior drugs related to immune abnormality

*Tabulation for publication (see the output plan in table of contents)

7. Change History

Date	Version	Author	Description
31-Aug-2020	1.0	PPD	Initial version
15-Sep-2021	2.0		3.The following definitions were added to the definition of terms: • The definition of "observation period at the time of first vaccination" was added. • The definition of "observation period at the time of second vaccination" was added. 4.2.The definitions of analysis populations/sites were modified. 4.3.1.The order of priority of exclusion criteria for subjects excluded from safety analysis was modified. 4.9.The definition of adverse reactions and adverse reactions was reorganized as 4.9.1., and the handling of 4.9.2. Timing of onset of adverse reactions and 4.9.3. Grade0 adverse reactions was added. 4.10.3.Herpes zoster was added. 4.10.4.Persons Requiring Caution and Immunologic Abnormalities Herpes zoster was added. 4.11.The following definitions were modified in the definition of terms: • The definition of "immunosuppression" was modified. 6.2.3.Characteristics of subjects (presence or absence of applicable persons requiring caution) was added.
06-Sep-2022	Ver3.0		4.6.Handling of presence or absence Added coding to presence/absence judgment. 5.3 Display of results Added odds ratio. 5.4.1.1.Exploratory analysis of influential factors

			Deleted the explanation that univariate analysis will be performed in the stability report before the final report. 6.2.1 Subject composition ratio Deletion of tabulation by vaccination frequency 6.2.2. Background of subjects The formula for calculating vaccination interval of this vaccine was corrected. The number of days category was changed. 6.3.2 Time to adverse reaction The initial date of reckoning for calculation was corrected. 6.6.4. Underlying disease It was added that underlying diseases related to immune abnormality are included in Underlying disease. Appendix Correction of handling of drugs used 6.6.6 Previous drugs, 6.6.7 Drugs used Drug category was added to summary table. 3. Definition of Terms, 4.2. Analysis populations/Sites, Supplementary explanation was added. Other clerical errors were corrected, and descriptions were adjusted.
12-May-2023	Ver4.0	PPD	6.2.2. Changed the combination of vaccination frequency and vaccine category in vaccinations other than this vaccine (Table1.04) by demographic characteristics of subjects 6.3.1. Addition of a form to tabulate subjects with immune abnormality to the list of occurrence status of adverse reactions by demographic characteristics of subjects (Table2.01.5) 6.3.4. Addition of a form to tabulate subjects with immune abnormality to the occurrence status of serious adverse reactions/adverse reactions by sex (Table2.04.5)

			Addition of occurrence status of adverse reactions/infections in post-marketing surveillance, etc. (Appendix Form 2, Appendix Form 15) A separate table was added to the occurrence of adverse reactions and infections in the additional pharmacovigilance plan. 6.6.10. Addition of occurrence of adverse reactions by underlying disease/condition related to immune abnormality (Table2.24) 6.6.11. Addition of occurrence of adverse reactions by previous drug (drug that may affect immunity) (Table2.25) Correction of other clerical errors and description adjustment
8-Sep-2023	Ver5.0	PPD	4.3.1. Change of subjects excluded from safety analysis. Deletion of "no visit after the date of first vaccination" from reasons for exclusion from safety analysis 6.2.1. Addition of age category 3 to subject composition ratio (response to the expansion of indications) 6.2.2. Addition of category of vaccination interval of less than 27 days to subject demographics 6.2.4. Addition of subject demographics (reason for vaccination) (response to the expansion of indications) 6.5. Subject demographics Subject demographics List of subject demographics. Data on administration of this vaccine (Listing8) and data on administration of drugs other than this vaccine (Listing9) were separated from Listing3.
13 Sep 2024	Ver6.0		Change of the approver of the cover 4.9.2 Addition of handling of adverse event onset date unknown in tabulation (number of doses, specific/non-specific category)

			6.2.2. Deletion of subtabulation of vaccination other than this vaccine for “Other” (presented separately), addition of designation of the number of digits of drug code Deletion of tabulation of adverse reactions in 6.3.4 and 6.3.5 (tabulation items not in RMP or protocol)
12 Aug 2025	Ver7.0	PPD	Change of the approver of the cover page 6.6.1 - 6.6.3 Logistic regression analysis Change of items (variables) Tables 2.14 - 2.16 6.6.3 Addition of explanation about selection of search variables for multivariate analysis Listing1 Addition of adverse event onset date and LLT (Mock) Description adjustment

8. Appendix A Handling of drug category by administration timing

Drug category by administration timing shall be handled as follows.

◆Prerequisites

The categories of prior drugs, drugs used, and subsequent therapy shall be in accordance with the definitions.

◆Definitions of prior drugs, prior therapies, vaccines used (other than this vaccine), drugs used, therapies used (other than drugs), and subsequent therapies

Prior drugs, prior therapies: Drugs/therapies considered to affect immunity that were used before the day of the first vaccination with this vaccine.

Vaccines used (other than this vaccine), drugs used, and therapies used (other than drugs): Vaccines/drugs/therapies used during the observation period.

Subsequent therapies: Drugs used outside the observation period after the date of vaccination with this vaccine.

*This investigation will not use data of the drug category “subsequent treatment.”

◆Definition of prior drugs

From among the drugs listed in the column of “prior drugs (drugs that may affect immunity)” in CRF, drugs other than the following will be used.

- Date of first vaccination with this vaccine $\leq$ date of start of administration of drugs other than this vaccine

However, if only a partial date is given, the part given will be used to determine the prior drugs.

◆Definition of prior therapy

Treatment excluding the following from the therapies listed in the column of "prior therapy (therapy that may affect immunity)" in CRF.

- Date of first this vaccine vaccination $\leq$ Date of start of therapy other than this vaccine

However, if only a partial date is given, the part given should be used to determine the prior drug.

◆Definition of vaccine used

Of the vaccines listed in the column of “Vaccines used (vaccines other than this vaccine)” in CRF, vaccines administered during the observation period excluding the following will be used.

- Date of vaccination with any vaccine other than this vaccine < date of first vaccination with this vaccine
- Date of second vaccination with this vaccine + 29 < date of vaccination with any vaccine other than this vaccine
- “Date of first vaccination with this vaccine + 29 < date of vaccination with any vaccine other than this vaccine ” and “ date of vaccination with any vaccine other than this vaccine < date of second vaccination with this vaccine (determined only if 2 doses of this vaccine are given)”

However, if only a partial date is given, the part given should be used to determine the vaccine used.

◆Definition of drugs used

Drugs other than the following are listed in the columns of “previous drugs (drugs that may affect immunity)” and “used drugs” in CRF.

- Date of completion of administration of drugs other than this vaccine < date of first this vaccine vaccination
- Date of second this vaccine vaccination + 29 < date of start of administration of drugs other than this vaccine
- “date of first this vaccine vaccination + 29 < date of start of administration of drugs other than this vaccine ” and “ date of completion of administration of drugs other than this vaccine < date of second this vaccine vaccination (determined only in subjects who received 2 doses of this vaccine)”
- The start and end dates of administration of drugs other than this vaccine listed in the "Drugs used previously (drugs that may affect immunity)" section of CRF are unknown.
- The start date of administration of drugs other than this vaccine $\leq$ the date of first vaccination with this vaccine in the "Drugs used previously (drugs that may affect immunity)" section of CRF and the end date of administration of drugs other than this vaccine is unknown.

However, if only a partial date is given, the part given should be used to determine the drug used.

◆Definition of administered therapy

From the drugs listed in the "Prior therapy (therapies that may affect immunity)" and "Administered therapy (other than drugs)" sections of CRF, therapies other than those listed below should be used.

- End date of therapy < Date of first this vaccine vaccination

- Date of second vaccination of this vaccine + 29 < Start date of therapy
- "Date of first vaccination of this vaccine + 29 < Start date of therapy" and "End date of therapy < Date of second vaccination of this vaccine (determined only when 2 doses of this vaccine are given)"
- The start date and end date of therapy for "prior therapy (therapy that may affect immunity)" in CRF are unknown.

However, if only a partial date is given, the part given should be used to determine the drug used.

Appendix 3

For
Reexamination

Case No.

212853—

Shingrix for Intramuscular Injection Drug Use Investigation Case Report Form

Medical Institution Name	
Department Name	
Investigating Physician Name	
Identification Number	Do not input information that identifies individuals, such as the name, address, date of birth, initials, or medical record number of the vaccinated person.
Sex	☐ Male ☐ Female
Year of Birth or Age at First Dose of This Vaccine	☐ Calendar year _____ year of birth or ☐ Age at first dose of this vaccine _____ years

<Instructions for Entry>

- (1) The tabulation and analysis results of this case report form will be reported to the Pharmaceuticals and Medical Devices Agency. Please ensure that no entry items are left blank.
- (2) After confirming the entered information, please sign the physician name field.
- (3) Do not enter any personally identifiable information about the vaccine recipient in this form, such as name, address, date of birth, initials, or medical record number.

Physician Name
Entry Field

Investigating
Physician
Name

GlaxoSmithKline K.K.

Revision date: May 19, 2023 (Version 4)

[Vaccine Recipient Background]

Please enter the status at the time of the first dose of this vaccine.

Reason for Vaccination (Multiple selections allowed)	☐ Age at first dose of this vaccine (50 years or older) ☐ Immunodeficiency due to disease or treatment Select "Yes" for "Presence of immune abnormality" and enter the disease or treatment. ☐ Reduced immune function due to disease or treatment Select "Yes" for "Presence of immune abnormality" and enter the disease or treatment. ☐ May have reduced immune function due to disease or treatment Enter the disease or treatment in "Underlying diseases," "Medications used," and "Therapies performed." ☐ Other than the above, the physician judged that vaccination with this vaccine was necessary ()
History of Herpes Zoster Vaccination Other Than This Vaccine	☐ No ☐ Yes ☐ Unknown
History of Herpes Zoster	☐ No ☐ Yes ☐ Unknown
Need for Precaution Before Vaccination	☐ No ☐ Yes
Presence of Immune Abnormality	☐ No ☐ Yes If yes, enter the disease, medication, or treatment causing the immune abnormality in "Underlying diseases related to immune abnormality," "Previous medications (medications considered to affect immunity)" P3, and "Previous therapies (therapies considered to affect immunity)" P4.

Underlying Diseases Related to Immune Abnormality		☐ No ☐ Yes If yes, enter the disease name below.	
		Underlying Diseases Related to Immune Abnormality	
Underlying Diseases	Cardiovascular diseases Renal diseases Hepatic diseases Blood disorders Thrombocytopenia or coagulation disorders Allergies (foods, drugs, etc.) Other	☐ No ☐ Yes If yes, enter the disease name below.	
		Underlying Diseases	
Medical History	Convulsions Other Other	☐ No ☐ Yes If yes, enter the disease name below.	
		Past Medical Conditions	

Note: <Underlying Diseases>

In this survey, please enter as "underlying diseases" any diseases or symptoms present at the time of the first dose of this vaccine. Please confirm and enter whether renal impairment, hepatic impairment, or any other disease was present at the time of the first dose. For allergies to foods, drugs, environmental substances, or allergies associated with prior vaccinations, enter them in the underlying diseases field as "Allergy (e.g., egg, mites, influenza vaccine, etc.)."

[Previous Medications (Medications Considered to Affect Immunity)]

Please enter whether there was administration of medications considered to affect immunity that had been used before the first dose of this vaccine or are still being continued, and the medication name.

Presence of Previous Medications	☐ No ☐ Yes [If yes, enter the details below.]	
Medication Name	Start Date of Administration	End Date of Administration
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day
	☐ Unknown ☐ Calendar year year__month__day	☐ Administration ongoing ☐ Calendar year year__month__day

[Previous Therapies (Therapies Considered to Affect Immunity)]

Please enter whether there were therapies considered to affect immunity that had been performed before the first dose of this vaccine or are still being continued, and the therapy name.

Presence of Previous Therapies		
Therapy Name	Start Date of Therapy	End Date of Therapy
☐ Dialysis	☐ Unknown ☐ Calendar year _____year____month____day	☐ Administration ongoing ☐ Calendar year _____year____month____day
☐ Radiation therapy	☐ Unknown ☐ Calendar year _____year____month____day	☐ Administration ongoing ☐ Calendar year _____year____month____day
☐ Anticoagulant therapy	☐ Unknown ☐ Calendar year _____year____month____day	☐ Administration ongoing ☐ Calendar year _____year____month____day
☐ Surgery / Other []	☐ Unknown ☐ Calendar year _____year____month____day	☐ Administration ongoing ☐ Calendar year _____year____month____day
☐ Surgery / Other []	☐ Unknown ☐ Calendar year _____year____month____day	☐ Administration ongoing ☐ Calendar year _____year____month____day
☐ Surgery / Other []	☐ Unknown ☐ Calendar year _____year____month____day	☐ Administration ongoing ☐ Calendar year _____year____month____day

[Vaccination Status of This Vaccine]

Please enter the status at the time of the first dose of this vaccine.

Vaccination (First Dose)

Vaccination Date	Calendar year year month day
Body Temperature Before Vaccination with This Vaccine	_____ . _____ °C ☐ Unknown
Dose Administered	☐ 0.5 mL ☐ Other (mL)
Injection Site	☐ Upper arm (☐ Right • ☐ Left) ☐ Other () (☐ Right • ☐ Left)
Route of Administration	☐ Intramuscular ☐ Other ()
Manufacturing Number (Lot Number) of This Vaccine	
Symptoms Immediately Before Vaccination (such as feeling unwell on the day) Presence/Absence	☐ No ☐ Yes ()

[Vaccination Status of This Vaccine]

Please enter the status at the time of the second dose of this vaccine.

If the second dose was not administered, please enter the reason in the "Reason for Vaccination Interruption" field.

Note: If "Adverse event occurred" is selected, please enter details of the adverse event in the [Adverse Events] section on Pages 10 and 11.

Vaccination (Second Dose)

Vaccination Date	☐ Calendar year year month day ☐ Not vaccinated →Please enter in "Reason for Vaccination Interruption"
Body Temperature Before Vaccination with This Vaccine	_____ . _____ °C ☐ Unknown
Dose Administered	☐ 0.5 mL ☐ Other (mL)
Injection Site	☐ Upper arm (☐ Right • ☐ Left) ☐ Other () (☐ Right • ☐ Left)
Route of Administration	☐ Intramuscular ☐ Other ()
Manufacturing Number (Lot Number) of This Vaccine	
Symptoms Immediately Before Vaccination (such as feeling unwell on the day) Presence/Absence	☐ No ☐ Yes ()

Reason for Vaccination Interruption

Reason the Second Dose Was Not Administered (Multiple selections allowed)	☐ Adverse event occurred⇒P10, 11 Enter details of the adverse event in the [Adverse Events] section. ☐ Pregnancy⇒P9 Enter details of the pregnancy in the [Pregnancy] section. ☐ Vaccinated at another medical institution ☐ Received another vaccine ☐ No visit after the first vaccination date ☐ No visit from midway onward ☐ Vaccine recipient-related reason other than the above ☐ Physician's judgment other than the above
--	--

[Concomitant Vaccines (Vaccines Other Than This Vaccine)]

Please enter whether any vaccines were administered and the vaccine names during the 30 days from the first dose date of this vaccine (with the vaccination date counted as Day 1) and during the 30 days from the second dose date of this vaccine (with the vaccination date counted as Day 1), including concomitantly administered vaccines.

Presence of Concomitant Vaccines	☐ No	☐ Yes	[If yes, enter the details below.]
Vaccine Name	Vaccination Date		Injection Site
☐ Influenza vaccine	Calendar year _____ _____year_____month_____day		☐ Upper arm ☐ Other [_____] ☐ Right • ☐ Left
☐ Pneumococcal vaccine	Calendar year _____ _____year_____month_____day		☐ Upper arm ☐ Other [_____] ☐ Right • ☐ Left
☐ Other [_____] [_____]	Calendar year _____ _____year_____month_____day		☐ Upper arm ☐ Other [_____] ☐ Right • ☐ Left
☐ Other [_____] [_____]	Calendar year _____ _____year_____month_____day		☐ Upper arm ☐ Other [_____] ☐ Right • ☐ Left
☐ Other [_____] [_____]	Calendar year _____ _____year_____month_____day		☐ Upper arm ☐ Other [_____] ☐ Right • ☐ Left

[Concomitant Medications]

Please enter whether any medications were administered and the medication names during the 30 days from the first dose date of this vaccine (with the vaccination date counted as Day 1) and during the 30 days from the second dose date of this vaccine (with the vaccination date counted as Day 1).

If a previous medication (a medication considered to affect immunity) is still being administered after the first dose date of this vaccine, **re-entry here is not necessary.**

Note: <Reason for Administration>

Note 1: If administered for an underlying disease (a disease or symptom present before the start of vaccination with this vaccine), select "Treatment for underlying disease" and enter the corresponding disease name in the [Vaccine Recipient Background] "Underlying diseases" field on Page 2.

Note 2: If administered for an adverse event (a disease or symptom that developed after the start of vaccination with this vaccine), select “Treatment for adverse event” and enter details of the adverse event in the [Adverse Events] section on Pages 10 to 13.

Note 3: For prophylactic administration, select "Other" and enter details in parentheses.

Presence of Concomitant Medications	☐ No	☐ Yes	[If yes, enter the details below.]
Medication Name	Start Date of Administration	End Date of Administration	Reason for Administration
	☐ Before the start of the first dose ☐ Calendar year ____ year ____ month ____ day	☐ Administration ongoing ☐ Calendar year ____ year ____ month ____ day	☐ Treatment for underlying disease* ¹ ☐ Treatment for adverse event* ² ☐ Other* ³ ()
	☐ Before the start of the first dose ☐ Calendar year ____ year ____ month ____ day	☐ Administration ongoing ☐ Calendar year ____ year ____ month ____ day	☐ Treatment for underlying disease* ¹ ☐ Treatment for adverse event* ² ☐ Other* ³ ()
	☐ Before the start of the first dose ☐ Calendar year ____ year ____ month ____ day	☐ Administration ongoing ☐ Calendar year ____ year ____ month ____ day	☐ Treatment for underlying disease* ¹ ☐ Treatment for adverse event* ² ☐ Other* ³ ()
	☐ Before the start of the first dose ☐ Calendar year ____ year ____ month ____ day	☐ Administration ongoing ☐ Calendar year ____ year ____ month ____ day	☐ Treatment for underlying disease* ¹ ☐ Treatment for adverse event* ² ☐ Other* ³ ()

[Therapies Performed (Other Than Medications)]

Please enter whether any therapies (other than medications) were performed and the therapy names during the 30 days from the first dose date of this vaccine (with the vaccination date counted as Day 1) and during the 30 days from the second dose date of this vaccine (with the vaccination date counted as Day 1).

If a previous therapy (a therapy considered to affect immunity) is still being continued after the first dose date of this vaccine, re-entry here is not necessary.

Note: <Reason for Therapy>

Note 1: If performed for an underlying disease (a disease or symptom present before the start of vaccination with this vaccine), select "Treatment for underlying disease" and enter the corresponding disease name in the [Vaccine Recipient Background] "Underlying diseases" field on Page 2.

Note 2: If performed for an adverse event (a disease or symptom that developed after the start of vaccination with this vaccine), select "Treatment for adverse event" and enter details of the adverse event in the [Adverse Events] section on Pages 10 to 13.

Note3: When administering prophylactic treatment, select "Other" and enter details in the parentheses.

Presence of Therapies Performed	☐ No ☐ Yes [If yes, enter the details below.]		
Therapy Name	Start Date of Therapy	End Date of Therapy	Reason for Therapy
☐ Dialysis	☐ Before the start of the first dose ☐ Calendar year _____ year _____ month _____ day	☐ Administration ongoing ☐ Calendar year _____ year _____ month _____ day	☐ Treatment for underlying disease*1 ☐ Treatment for adverse event*2 ☐ Other ()
☐ Radiation therapy	☐ Before the start of the first dose ☐ Calendar year _____ year _____ month _____ day	☐ Administration ongoing ☐ Calendar year _____ year _____ month _____ day	☐ Treatment for underlying disease*1 ☐ Treatment for adverse event*2 ☐ Other ()
☐ Anticoagulant therapy	☐ Before the start of the first dose ☐ Calendar year _____ year _____ month _____ day	☐ Administration ongoing ☐ Calendar year _____ year _____ month _____ day	☐ Treatment for underlying disease*1 ☐ Treatment for adverse event*2 ☐ Other ()
☐ Surgery / Other []	☐ Before the start of the first dose ☐ Calendar year _____ year _____ month _____ day	☐ Administration ongoing ☐ Calendar year _____ year _____ month _____ day	☐ Treatment for underlying disease*1 ☐ Treatment for adverse event*2 ☐ Other ()

[Pregnancy] * Please complete only if the vaccine recipient is female.

Please enter whether vaccination was given to a pregnant woman or whether pregnancy occurred from the first dose date of this vaccine until the end of the observation period after the second dose (30 days after the second dose). If pregnant, enter the expected delivery date.

Around the expected delivery date, our medical representative will visit for follow-up.

Presence of Pregnancy	☐ No ☐ Yes : Due date: Calendar year year month day
-----------------------	--

[Adverse Events]

Note: <Definition of Adverse Events>

An adverse event is any unfavorable medical occurrence in a vaccine recipient and does not necessarily refer only to events that have a causal relationship with the vaccine. In other words, an adverse event is any unfavorable and unintended sign, symptom, disease, or abnormal laboratory finding that is temporally associated with vaccination, regardless of whether it is related to the vaccine.

<Safety Concerns>

- Shock, anaphylaxis
- Diseases suspected to involve immune mechanisms

<First Dose>

Specific Adverse Events

Please select whether any specific adverse events occurred and the applicable adverse events that developed during the 7 days after the first dose of this vaccine (from the vaccination date as Day 1 through Day 7). If "Yes," enter details in the adverse event field.

Presence of Specific Adverse Events	☐ No ☐ Yes [If yes, select below and enter in the adverse event entry field.		
Local Adverse Events	☐ Injection site pain ☐ Injection site redness ☐ Injection site swelling		
Systemic Adverse Events	☐ Myalgia	☐ Fatigue	☐ Headache
	☐ Chills	☐ Fever	☐ Nausea
	☐ Vomiting	☐ Diarrhea	☐ Abdominal pain
	☐ Chills	☐ Fever	☐ Nausea
	☐ Vomiting	☐ Diarrhea	☐ Abdominal pain

Non-specific Adverse Events

Select whether any adverse events other than the specific adverse events above (diseases, symptoms, abnormal laboratory values, etc.) developed up to 30 days after the first dose of this vaccine (with the vaccination date counted as Day 1), and enter details in the adverse event field, including the specific local and systemic adverse events above that developed after the first 7 days post-vaccination. Adverse events that occurred from the first dose until the second dose may be entered in the adverse event field.

Presence of Non-specific Adverse Events	☐ No ☐ Yes [If yes, enter in the adverse event field.
---	--

any inconsistency between these two, the Japanese version shall prevail.

[Adverse Events] Continued <First Dose>

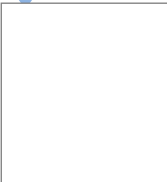
Please enter adverse events that developed up to 30 days after the first dose of this vaccine (with the vaccination date counted as Day 1). (Adverse events outside the observation period may also be included.)

If an adverse event that occurred after the first dose continued beyond the second dose or was judged to be part of the same adverse event series, re-entry in the <Second Dose> section on P13 is not necessary. Please enter it here.

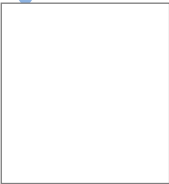
Note: Adverse event entry guidance: Please be sure to enter the diagnosis or symptom name. Enter the onset date, outcome, actual outcome date (or the date judged if the exact date cannot be identified), severity grade, seriousness, and causal relationship to this vaccine. If the event is judged serious, enter the reason it was considered serious; multiple reasons may be selected. For factors other than this vaccine suspected to be related, enter all relevant medications, diseases, procedures, and other factors for each adverse event.

Adverse Event Name	Onset Date	Outcome of Adverse Event	Outcome Date	Severity (Grade)	Seriousness	Reason Considered Serious	Causal Relationship to This Vaccine	Factors Other Than This Vaccine Suspected to Be Related (medications, diseases, procedures, etc.)
Please be sure to enter the diagnosis or symptom name Example: renal impairment	Please enter the onset date. Please enter the onset date.	Please enter the outcome.	Please enter the actual outcome date. If the exact date cannot be identified, enter the date judged. If the exact date cannot be identified, enter the date judged.	Please enter the severity (grade) assessment.	Please enter seriousness.	If judged serious, please enter the reason it was considered serious. (Multiple entries allowed) (Multiple entries allowed)	Please enter whether there is a reasonable causal relationship with this vaccine.	☐ No ☐ Incidental ☒ Yes ☐ Unknown
<u>Diagnosis or Symptom Name</u> <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above] <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above]	Calendar year _____ year _____ month _____ day	☐ Recovered ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown	Calendar year _____ year _____ month _____ day	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown	☒ Serious ☐ Non-serious ☐ Non-serious	☐ Results in death ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reactio	☒ Related ☐ Not related ☐ Not related	☐ No ☐ Incidental ☒ Yes ☐ Unknown ↓

any inconsistency between these two, the Japanese version shall prevail.

Adverse Event Name	Onset Date	Outcome of Adverse Event	Outcome Date	Severity (Grade)	Seriousness	Reason Considered Serious	Causal Relationship to This Vaccine	Factors Other Than This Vaccine Suspected to Be Related (medications, diseases, procedures, etc.)
Please be sure to enter the diagnosis or symptom name Example: renal impairment	Please enter the onset date. Please enter the onset date.	Please enter the outcome.	Please enter the actual outcome date. If the exact date cannot be identified, enter the date judged. If the exact date cannot be identified, enter the date judged.	Please enter the severity (grade) assessment.	Please enter seriousness.	If judged serious, please enter the reason it was considered serious. (Multiple entries allowed) (Multiple entries allowed)	Please enter whether there is a reasonable causal relationship with this vaccine.	☐ No ☐ Incidental ☒ Yes ☐ Unknown
<u>Diagnosis or Symptom Name</u> <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above] <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above]	Calendar year ____ year ____ month ____ day	☐ Recovered ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown	Calendar year ____ year ____ month ____ day	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown	☒ Serious ☐ Non-serious ☐ Non-serious	☐ Results in death ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction	☒ Related ☐ Not related ☐ Not related	☐ No ☐ Incidental ☒ Yes ☐ Unknown 

any inconsistency between these two, the Japanese version shall prevail.

Adverse Event Name	Onset Date	Outcome of Adverse Event	Outcome Date	Severity (Grade)	Seriousness	Reason Considered Serious	Causal Relationship to This Vaccine	Factors Other Than This Vaccine Suspected to Be Related (medications, diseases, procedures, etc.)
Please be sure to enter the diagnosis or symptom name Example: renal impairment	Please enter the onset date. Please enter the onset date.	Please enter the outcome.	Please enter the actual outcome date. If the exact date cannot be identified, enter the date judged. If the exact date cannot be identified, enter the date judged.	Please enter the severity (grade) assessment.	Please enter seriousness.	If judged serious, please enter the reason it was considered serious. (Multiple entries allowed) (Multiple entries allowed)	Please enter whether there is a reasonable causal relationship with this vaccine.	☐ No ☐ Incidental ☒ Yes ☐ Unknown
<u>Diagnosis or Symptom Name</u> <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above] <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above]	Calendar year ____ year ____ month ____ day	☐ Recovered ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown	Calendar year ____ year ____ month ____ day	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown	☒ Serious ☐ Non-serious ☐ Non-serious	☐ Results in death ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction	☒ Related ☐ Not related ☐ Not related	☐ No ☐ Incidental ☒ Yes ☐ Unknown 

[Adverse Events] Continued

<Second Dose>

Specific Adverse Events

Please select whether any specific adverse events occurred and the applicable adverse events that developed during the 7 days after the second dose of this vaccine (from the vaccination date as Day 1 through Day 7). If "Yes," enter details in the adverse event field.

Presence of Specific Adverse Events	☐ No ☒ Yes  If [yes], select the following and enter it in the adverse event entry field.
Local Adverse Events	☐ Injection site pain ☐ Injection site redness ☐ Injection site swelling
Systemic Adverse Events	☐ Myalgia ☐ Fatigue ☐ Headache ☐ Chills ☐ Fever ☐ Nausea ☐ Vomiting ☐ Diarrhea ☐ Abdominal pain

Non-specific Adverse Events

Select whether any adverse events other than the specific adverse events above (diseases, symptoms, abnormal laboratory values, etc.) developed up to 30 days after the second dose of this vaccine (with the vaccination date counted as Day 1), and enter details in the adverse event field, including the specific local and systemic adverse events above that developed after the first 7 days post-vaccination.

Presence of Non-specific Adverse Events	☐ 無 ☒ 有  [If applicable], please enter it in the adverse event entry field.
---	---

[Adverse Events] Continued <Second Dose>

Please enter adverse events that developed up to 30 days after the second dose of this vaccine (with the vaccination date counted as Day 1).

(Adverse events outside the observation period may also be included.)

If an adverse event that occurred after the first dose continued beyond the second dose or was judged to be part of the same adverse event series, re-entry here is not necessary.

any inconsistency between these two, the Japanese version shall prevail.

Adverse Event Name	Onset Date	Outcome of Adverse Event	Outcome Date	Severity (Grade)	Seriousness	Reason Considered Serious	Causal Relationship to This Vaccine	Factors Other Than This Vaccine Suspected to Be Related (medications, diseases, procedures, etc.)
Please be sure to enter the diagnosis or symptom name Example: renal impairment	Please enter the onset date. Please enter the onset date.	Please enter the outcome.	Please enter the actual outcome date. If the exact date cannot be identified, enter the date judged. If the exact date cannot be identified, enter the date judged.	Please enter the severity (grade) assessment.	Please enter seriousness.	If judged serious, please enter the reason it was considered serious. (Multiple entries allowed) (Multiple entries allowed)	Please enter whether there is a reasonable causal relationship with this vaccine.	☐ No ☐ Incidental ☒ Yes ☐ Unknown
<u>Diagnosis or Symptom Name</u> <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above] <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above]	Calendar year ____ year ____ month ____ day	☐ Recovered ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown	Calendar year ____ year ____ month ____ day	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown	☒ Serious ☐ Non-serious ☐ Non-serious	☐ Results in death ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction	☒ Related ☐ Not related ☐ Not related	☐ No ☐ Incidental ☒ Yes ☐ Unknown 

any inconsistency between these two, the Japanese version shall prevail.

Adverse Event Name	Onset Date	Outcome of Adverse Event	Outcome Date	Severity (Grade)	Seriousness	Reason Considered Serious	Causal Relationship to This Vaccine	Factors Other Than This Vaccine Suspected to Be Related (medications, diseases, procedures, etc.)
Please be sure to enter the diagnosis or symptom name Example: renal impairment	Please enter the onset date. Please enter the onset date.	Please enter the outcome.	Please enter the actual outcome date. If the exact date cannot be identified, enter the date judged. If the exact date cannot be identified, enter the date judged.	Please enter the severity (grade) assessment.	Please enter seriousness.	If judged serious, please enter the reason it was considered serious. (Multiple entries allowed) (Multiple entries allowed)	Please enter whether there is a reasonable causal relationship with this vaccine.	☐ No ☐ Incidental ☒ Yes ☐ Unknown
<u>Diagnosis or Symptom Name</u> <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above] <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above]	Calendar year ____ year ____ month ____ day	☐ Recovered ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown	Calendar year ____ year ____ month ____ day	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown	☒ Serious ☐ Non-serious ☐ Non-serious	☐ Results in death ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction	☒ Related ☐ Not related ☐ Not related	☐ No ☐ Incidental ☒ Yes ☐ Unknown 

any inconsistency between these two, the Japanese version shall prevail.

Adverse Event Name	Onset Date	Outcome of Adverse Event	Outcome Date	Severity (Grade)	Seriousness	Reason Considered Serious	Causal Relationship to This Vaccine	Factors Other Than This Vaccine Suspected to Be Related (medications, diseases, procedures, etc.)
Please be sure to enter the diagnosis or symptom name Example: renal impairment	Please enter the onset date. Please enter the onset date.	Please enter the outcome.	Please enter the actual outcome date. If the exact date cannot be identified, enter the date judged. If the exact date cannot be identified, enter the date judged.	Please enter the severity (grade) assessment.	Please enter seriousness.	If judged serious, please enter the reason it was considered serious. (Multiple entries allowed) (Multiple entries allowed)	Please enter whether there is a reasonable causal relationship with this vaccine.	☐ No ☐ Incidental ☒ Yes ☐ Unknown
<u>Diagnosis or Symptom Name</u> <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above] <Options> Injection site pain Injection site redness Injection site swelling Myalgia Fatigue Headache Chills Fever Nausea Vomiting Diarrhea Abdominal pain [Symptoms other than the above]	Calendar year ____ year ____ month ____ day	☐ Recovered ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown ☐ Recovering ☐ Not recovered ☐ Sequelae ☐ Death ☐ Unknown	Calendar year ____ year ____ month ____ day	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown	☒ Serious ☐ Non-serious ☐ Non-serious	☐ Results in death ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction ☐ Is life-threatening ☐ Requires hospitalization for treatment or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Results in a congenital anomaly or birth defect ☐ Other medically important event or reaction	☒ Related ☐ Not related ☐ Not related	☐ No ☐ Incidental ☒ Yes ☐ Unknown 

[Adverse Events] Continued

<Severity>

Adverse Event Name	Grade	
Injection site redness Injection site swelling	0	Less than 2 cm in diameter
	1	Diameter of 2 cm or more and 5 cm or less
	2	Diameter greater than 5 cm and less than or equal to 10 cm
	3	Diameter exceeds 10 cm
Fever	0	Less than 37.5°C
	1	37.5°C–38.0°C
	2	38.1°C–39.0°C
	3	39.0° C 超
Other adverse events	0	Normal (no symptoms)
	1	Mild: easily tolerated
	2	Moderate: interferes with usual activities
	3	Severe: unable to perform usual daily activities

<Definition of Serious Adverse Events>

A serious adverse event means any untoward medical occurrence following administration of a vaccine, regardless of dose, that meets any of the following criteria: See the listed criteria below.

(1) Results in death

(2) Is life-threatening

Here, "life-threatening" means that the vaccine recipient was at risk of death at the time of the event; it does not mean that the event might have caused death if it had been more severe.

Here, "life-threatening" means that the vaccine recipient was at risk of death at the time of the event; it does not mean that the event might have caused death if it had been more severe.

Here, "life-threatening" means that the vaccine recipient was at risk of death at the time of the event; it does not mean that the event might have caused death if it had been more severe.

(3) Requires hospitalization for treatment or prolongation of existing hospitalization

(4) Results in persistent or significant disability/incapacity

(5) Results in a congenital anomaly or birth defect

(6) Is another medically important event or reaction

In this case, even if the event does not immediately threaten life or result in death or hospitalization, it should be considered serious if it may jeopardize the vaccine recipient or may require intervention or treatment to prevent one of the outcomes listed above. Whether such a condition is medically important should be judged based on medical and scientific evidence. Examples include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood disorders or convulsions not resulting in hospitalization, and drug dependence or drug abuse.

In this case, even if the event does not immediately threaten life or result in death or hospitalization, it should be considered serious if it may jeopardize the vaccine recipient or may require intervention or treatment to prevent one of the outcomes listed above. Whether such a condition is medically important should be judged based on medical and scientific evidence. Examples include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood disorders or convulsions not resulting in hospitalization, and drug dependence or drug abuse.

In this case, even if the event does not immediately threaten life or result in death or hospitalization, it should be considered serious if it may jeopardize the vaccine recipient or may require intervention or treatment to prevent one of the outcomes listed above. Whether such a condition is medically important should be judged based on medical and scientific evidence. Examples include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood disorders or convulsions not resulting in hospitalization, and drug dependence or drug abuse.

Note: <Definition of Serious Adverse Events> A serious adverse event is any unfavorable medical occurrence following vaccination, regardless of dose, that meets one of the following criteria: (1) results in death; (2) is life-threatening, meaning the vaccine recipient was at immediate risk of death at the time of the event, not hypothetically if it had been more severe; (3) requires hospitalization for treatment or prolongation of existing hospitalization; (4) results in persistent or significant disability/incapacity; (5) results in a congenital anomaly or birth defect; or (6) is another medically important event or reaction. Medically important events may not immediately be life-threatening or result in death or hospitalization but may jeopardize the vaccine recipient or require intervention to prevent one of the outcomes above. Examples include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood disorders or convulsions not resulting in hospitalization, and drug dependence or drug abuse.