

## NON-INTERVENTIONAL STUDY INTERIM REPORT 1

### Study Information

<b>Title</b>	Observational Cohort Study of Zavegepant Safety in Pregnancy within a US Claims Database
<b>Protocol number</b>	C5301027
<b>Version identifier of the study report</b>	1.0
<b>Date</b>	23 April 2025
<b>EU Post Authorization Study (PAS) register number</b>	EUPAS1000000408
<b>Active substance</b>	Zavegepant World Health Organization Anatomical Therapeutic Chemical code N02CD08
<b>Medicinal product</b>	ZAVZPRET™
<b>Research question and objectives</b>	<p><u>Research question:</u></p> <p>Is there an increased risk of adverse maternal and/or infant outcomes in individuals with migraine exposed to zavegepant during pregnancy compared to individuals with migraine unexposed to zavegepant in pregnancy?</p> <p><u>Primary objectives:</u></p> <p>1. To estimate the prevalence of major congenital malformation (MCM) births among pregnant individuals with migraine who are (1) exposed to zavegepant (exposed cohort), (2) unexposed to zavegepant (treated comparator cohort), and (3) unexposed to migraine treatment (untreated comparator cohort).</p> <p>2. To estimate the relative risk of MCM births in the exposed cohort versus the comparator cohorts.</p>

	<p><u>Secondary objectives:</u></p> <p>1. To estimate the prevalence of the following secondary outcomes in the 3 study cohorts: spontaneous abortions, pregnancy complications (pre-eclampsia, eclampsia, gestational diabetes, gestational hypertension), stillbirths, preterm births, and small for gestational age (SGA) births.</p> <p>2. To estimate the relative risk of each of the secondary outcomes in the exposed cohort versus the comparator cohorts.</p> <p><u>Interim report objectives:</u></p> <p>To monitor the cumulative accrual of eligible patients, to describe cohort characteristics, and to summarize the number of claims-identified outcome events in the 3 study cohorts.</p>
<b>Country of study</b>	United States
<b>Authors</b>	<p>Monica Bertoia, MPH, PhD  Director, Safety Surveillance Research  Worldwide Medical &amp; Safety  Pfizer Inc.  66 Hudson Boulevard East  New York, NY 10001, USA  Telephone: (617) 817-6148  Email: monica.bertoia@pfizer.com</p> <p>Rachel Ogilvie, PhD, MPH  Senior Epidemiologist  Optum Epidemiology  1325 Boylston St  11th Floor  Boston, MA 02215, USA  Telephone: (617) 406-1175  Email: rachel.ogilvie@optum.com</p> <p>Jessica Franklin, PhD, FISPE  Vice President, Scientific Consulting  Optum Epidemiology  1325 Boylston St  11th Floor  Boston, MA 02215, USA  Telephone: (763) 330-5087  Email: jessica.franklin@optum.com</p>



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## 1. ABSTRACT (STAND-ALONE DOCUMENT)

## 2. LIST OF ABBREVIATIONS

Abbreviation	Definition
ACOG	American College of Obstetricians and Gynecologists
BRANY	Biomedical Research Alliance of New York
CGRP	Calcitonin gene-related peptide
CPT®	Current Procedural Terminology
DAPI	Optum Dynamic Assessment of Pregnancies and Infants
ED	Emergency department
EDC	Estimated date of conception
FDA	United States Food and Drug Administration
GPP	Guidelines for Good Pharmacoepidemiology Practices
HCPCS	Healthcare Common Procedure Coding System
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
IP	Inpatient
IRB	Institutional Review Board
ISPE	International Society for Pharmacoepidemiology
LMP	Last menstrual period
MCM	Major congenital malformation
NDC	National Drug Code
OP	Outpatient
ORD	Optum Research Database
PASS	Post-authorization safety study
PPV	Positive predictive value
SAP	Statistical analysis plan
SAS	Statistical Analysis System
SGA	Small for gestational age
SOP	Standard Operating Procedure
US	United States

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### 3. INVESTIGATORS

#### Principal Investigators of the Protocol

Name, degrees	Title	Affiliation
Monica Bertoia, MPH, PhD	Director, Safety Surveillance Research, Worldwide Medical & Safety	Pfizer Inc.
Jessica Franklin, PhD, FISPE	Vice President, Scientific Consulting	Optum Epidemiology

### 4. OTHER RESPONSIBLE PARTIES

Not applicable.



## 5. MILESTONES

Milestone	Planned date	Actual date	Comments
Date of IRB approval of protocol	01 November 2024	18 October 2024	
Start of data collection	01 January 2025	02 January 2025	01 January is a US holiday
Registration in the HMA-EMA Catalogues of RWD Studies	Prior to the start of data collection	10 December 2024	
Interim report 1	30 June 2025		
Interim report 2	30 June 2026		
Interim report 3	30 June 2027		
Interim report 4	30 June 2028		
Interim report 5	30 June 2029		
Interim report 6	30 June 2030		
End of data collection	01 January 2031 <sup>1</sup>		
Final report of study results	30 June 2032		

<sup>1</sup>This date refers to the date of the final data pull

HMA-EMA, Heads of Medicines Agencies-European Medicines Agency; IRB, institutional review board; RWD, real world date.

## 6. RATIONALE AND BACKGROUND

In March 2023, the United States (US) Food and Drug Administration (FDA) approved zavegepant ([ZAVZPRET™ label 2023](#)) for the acute treatment of migraine with or without aura in adults. Zavegepant is the first calcitonin gene-related peptide (CGRP) receptor antagonist available to patients as a nasal spray. CGRP receptor antagonists represent the newest class of migraine treatments that reduce pain through interfering with CGRP-induced vasodilation and inflammation ([Edvinsson et al. 2018](#)).

While no adverse developmental effects were observed in zavegepant animal studies, there are limited data on the safety of zavegepant use in pregnant individuals ([ZAVZPRET™ label 2023](#)). The purpose of this study is to assess the safety of zavegepant when used in pregnancy in terms of risk of major congenital malformations (MCMs), spontaneous abortion, pregnancy complications (pre-eclampsia, eclampsia, gestational diabetes, gestational hypertension), stillbirth, preterm births, and small-for-gestational-age (SGA) births.

This first of 6 annual interim reports summarizes the accrual of exposed pregnancies through 31 October 2024. This non-interventional study is designated as a post-authorization safety study (PASS) and is an FDA postmarketing requirement.

## 7. RESEARCH QUESTION AND OBJECTIVES

Research question:

Is there an increased risk of adverse maternal and/or infant outcomes in individuals with migraine exposed to zavegepant during pregnancy compared to individuals with migraine unexposed to zavegepant in pregnancy?

Primary objectives:

1. To estimate the prevalence of MCM births among pregnant individuals with migraine who are (1) exposed to zavegepant (exposed cohort), (2) unexposed to zavegepant (treated comparator cohort), and (3) unexposed to migraine treatment (untreated comparator cohort).
2. To estimate the relative risk of MCM births in the exposed cohort versus the comparator cohorts.

Secondary objectives:

1. To estimate the prevalence of the following secondary outcomes in the 3 study cohorts: spontaneous abortions, pregnancy complications (pre-eclampsia, eclampsia, gestational diabetes, gestational hypertension), stillbirths, preterm births, and SGA births.
2. To estimate the relative risk of each of the secondary outcomes in the exposed cohort versus the comparator cohorts.

Interim report objectives:

To monitor the cumulative accrual of eligible patients, to describe cohort characteristics, and to summarize the number of claims-identified outcome events in the 3 study cohorts.

## 8. AMENDMENTS AND UPDATES

**Table A. Amendments to the Protocol**

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
V4.0	31 January 2025	Substantial	4, 8, 9.1, 9.7.2.5	Removed the phrase "if sample size permits" from the comparative primary and secondary objectives	FDA 23 January 2025 comments
V4.0	31 January 2025	Substantial	9.3.2 (Table 6)	Outcome ascertainment window for pregnancy complications updated to begin at 20 weeks of gestation for consistency with published validated algorithms	Clarification
V4.0	31 January 2025	Substantial	9.7.1	Added a migraine medication utilization analysis to interim report 4	FDA 23 January 2025 comments
V4.0	31 January 2025	Substantial	9.7.2.1	Removed LASSO as a method to reduce the number of variables in the propensity score model	FDA 23 January 2025 comments
V4.0	31 January 2025	Substantial	Table 11, Table 12	Corrected ICD-10 code typo	FDA 23 January 2025 comments
V3.0	24 October 2024	Administrative	3	Updated primary Optum Epidemiology author from John Seeger to Jessica Franklin	Administrative update
V3.0	24 October 2024	Substantial	4, 8	Revised primary objectives to include the comparative MCM analysis	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	4, 9.5	Reverted back to original sample size calculations and target accrual that did not account for the proportion of patients that are medical record eligible and the proportion of patients for whom medical records are obtained	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	6.0	Revised end of data collection date to align with planned final data pull	Clarification
V3.0	24 October 2024	Substantial	8.0	Added hypothesis statements for the comparative objectives	FDA 10 October 2024 comments

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**Table A. Amendments to the Protocol**

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
V3.0	24 October 2024	Substantial	9.1	Clarified that the cohort entry date and pregnancy start date for each pregnancy will be the EDC, defined as 2 weeks after the estimated LMP	Clarification
V3.0	24 October 2024	Substantial	9.2.2	Clarified that the pregnancies exposed to other CGRP medications will not be included in the primary analysis, but will be included in a sensitivity analysis	Clarification
V3.0	24 October 2024	Substantial	9.2.3, 9.3.2.1	Revised MCM analyses to exclude pregnancies with teratogen exposure within a 5-half-life time window prior to EDC through the end of pregnancy (rather than through the end of the first trimester)	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	9.2.4	Clarified that pregnancies included in the zavegepant-exposed cohort may be exposed to migraine medications other than those used to define the treated comparator group	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	9.2.4, 9.2.5, 9.2.6, 9.2.10, 9.3.1.2	Removed ergots and topiramate from the treated comparator cohort because they are contraindicated in pregnancy and topiramate is indicated for migraine prevention not acute treatment	Methodological update
V3.0	24 October 2024	Substantial	9.2.10	Clarified that the nonmigraine cohort will exclude pregnancies with a dispensing of zavegepant, triptans, or ditans during outcome-specific exposure windows	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	9.3.1	Clarified that the definition of exposure for migraine medications applies to acute (as needed) and preventive migraine medications, including CGRP medications	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	9.3.1.2	Reorganized comparator treatment list for clarity	Clarification
V3.0	24 October 2024	Substantial	9.3.2	Noted that some secondary outcomes may be adjudicated in the final report if imbalances are observed in interim reports	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	9.3.2	Designated Algorithm B for the preterm birth outcome as the primary algorithm, and algorithms A and C as sensitivity analyses	Methodological update

**Table A. Amendments to the Protocol**

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
V3.0	24 October 2024	Substantial	9.3.2.6	Corrected definition of preterm birth from <35 gestational weeks to <37 gestational weeks	Correction
V3.0	24 October 2024	Substantial	9.3.3, Annex 5	Removed gestational diabetes and gestational hypertension from list of covariates because these are now study outcomes	Correction
V3.0	24 October 2024	Substantial	9.7.2.1	Revised from 1 propensity score calculated for each pregnancy to 3: 1 based on exposure in the first trimester, 1 based on exposure within the first 20 gestational weeks, and 1 based on exposure during the full pregnancy period.	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	9.7.2.3	Clarified that if propensity score weighting is used instead of matching, propensity scores will be used to calculate IPTW weights for estimation of the average treatment effect among the treated (ATT)	FDA 10 October 2024 comments
V3.0	24 October 2024	Substantial	9.7.4.10	Added a quantitative bias analysis using the PPV from MCM adjudication	Clarification
V3.0	24 October 2024	Substantial	Annex 5	Removed repeated drugs	Correction
V2.0	01 June 2024	Administrative	6.0	Noted date of draft protocol submission in milestones table	Administrative update
V2.0	01 June 2024	Administrative	6.0	Revised end of data collection to align with date of final report	Administrative update
V2.0	01 June 2024	Substantial	9.2.6	Added untreated comparator group	FDA 26 April 2024 comments
V2.0	01 June 2024	Substantial	9.3.2	Added gestational diabetes, gestational hypertension, and preterm birth as outcomes	FDA 26 April 2024 comments
V2.0	01 June 2024	Substantial	9.2.8	Changed definition of pregnancy start to EDC rather than last menstrual period (LMP)	FDA 26 April 2024 comments
V2.0	01 June 2024	Substantial	9.2.1	Expanded inclusion criteria to include individuals 15-50 years old (rather than 18-49 years old)	FDA 26 April 2024 comments

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**Table A. Amendments to the Protocol**

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
V2.0	01 June 2024	Substantial	9.2.2	Updated exclusion criteria to exclude pregnancies with exposure to any CGRP medication (rather than CGRP receptor antagonist)	FDA 26 April 2024 comments
V2.0	01 June 2024	Substantial	9.5	Updated sample size calculation	FDA 26 April 2024 comments
V2.0	01 June 2024	Substantial	9.2.2, 9.2.3, 9.2.4, 9.2.5, 9.2.6, 9.2.10	Updated exposure definitions	FDA 26 April 2024 comments
V2.0	01 June 2024	Substantial	9.7.4.	Edited sensitivity analyses	FDA 26 April 2024 comments

## 9. RESEARCH METHODS

### 9.1. Study Design

This is an observational cohort study using an existing US-based health insurance claims database containing prospectively collected data. Three study cohorts of pregnancies were identified among individuals with migraine: a cohort of zavegepant-exposed pregnancies and 2 comparator groups of pregnancies exposed to other migraine therapies and unexposed to migraine therapies, respectively. The cohort entry date (i.e., index date) and pregnancy start date for each pregnancy was the estimated date of conception (EDC), defined as 2 weeks after the estimated first day of the last menstrual period (LMP). The primary outcome was MCM, and secondary outcomes were spontaneous abortion, pregnancy complications (pre-eclampsia, eclampsia, gestational diabetes, gestational hypertension), stillbirth, preterm birth, and SGA. The interim analyses were descriptive and counted the number of outcomes in each study cohort. No propensity score matching was conducted in this interim report.

### 9.2. Setting

The base population for this interim report included all pregnancies among individuals with migraine with an EDC between 09 March 2023 and 31 October 2024 within the US-based health insurance claims database. Individuals could contribute multiple pregnancy episodes.

### 9.3. Subjects

#### 9.3.1. Inclusion Criteria

Pregnancies were required to meet all of the following criteria to be eligible for inclusion in the study:

1. Age 15-50 years at EDC

2. EDC during the study period (09 March 2023 to 31 October 2024)
3. Continuous health plan enrollment with medical and pharmacy benefits during the 6-month period before and including EDC

### 9.3.2. Exclusion Criteria

Pregnancies exposed to a CGRP receptor antagonist other than zavegepant (i.e., rimegepant, ubrogepant, atogepant) or a CGRP monoclonal antibody (i.e., erenumab, fremanezumab, galcanezumab, eptinezumab) during pregnancy were excluded from the study. Exposure periods for each CGRP medication were defined for each pregnancy using the date of dispensing or administration and the days' supply or recommended administration schedule plus 5 times the half-life of the therapy, rounded up to the nearest whole day. Half-lives for these drugs can be found in the statistical analysis plan (SAP), which is dated, filed and maintained by the sponsor.

In the final study report, pregnancies with exposure to known teratogens, pregnancies with infections known to cause congenital anomalies, and infants with syndromic or chromosomal anomalies will be excluded from the analysis of MCM. These exclusions were not applied in this interim report.

### 9.3.3. Pregnancy Identification

Published algorithms were used to identify pregnancies ([Bertoia et al. 2022](#)). Pregnancies were identified based on the presence of either International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Z3A codes or pregnancy outcome codes. Z3A codes denote weeks of gestation; for example, Z3A.20 denotes 20 weeks' gestation and Z3A.25 denotes 25 weeks' gestation. Pregnancy outcome codes (e.g., delivery, cesarean section, spontaneous abortion) included ICD-10-CM diagnosis or procedure codes, Current Procedural Terminology (CPT®) codes<sup>1</sup>, and Healthcare Common Procedure Coding System (HCPCS) codes.

The pregnancy start date was the EDC, defined as 2 weeks after the LMP. Published, validated algorithms were used to estimate LMP ([Chomistek et al. 2023](#)). These algorithms used ICD-10-CM Z3A diagnosis codes denoting weeks of gestation. For example, if the code Z3A.12 (12 weeks gestation) is observed on 26 March 2023, the LMP is estimated as 12 weeks prior or 01 January 2023 ([Bertoia et al. 2022](#)). For the 14% of pregnancies without Z3A codes, Optum employed outcomes-based algorithms that estimate the LMP by counting back the number of weeks from the occurrence of the outcome, with different outcomes assigned different weeks of gestation. A list of pregnancy dates and definitions

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can be found in Table B. Additional information about pregnancy identification can be found in the protocol and SAP.

**Table B. Pregnancy Dates**

Date	Definition
LMP	<ul style="list-style-type: none"> <li>First day of last menstrual period</li> <li>0 gestational weeks<sup>0/7 days</sup></li> </ul>
Gestational age	<ul style="list-style-type: none"> <li>Weeks of gestation</li> <li>Anchored by LMP</li> <li>Number of completed weeks elapsed after LMP</li> </ul>
Conception	<ul style="list-style-type: none"> <li>Typically estimated as LMP + 2 weeks</li> <li>2 gestational weeks<sup>0/7 days</sup></li> </ul>
First trimester	<ul style="list-style-type: none"> <li>Begins at EDC</li> <li>Ends at 13 weeks<sup>6/7 days</sup></li> </ul>
Second trimester	<ul style="list-style-type: none"> <li>Begins at 14 weeks<sup>0/7 days</sup></li> <li>Ends on 27 weeks<sup>6/7 days</sup></li> </ul>
Third trimester	<ul style="list-style-type: none"> <li>Begins at 28 weeks<sup>0/7 days</sup></li> <li>Ends at pregnancy outcome</li> </ul>
Pregnancy period	<ul style="list-style-type: none"> <li>Begins at date of conception</li> <li>Ends at pregnancy outcome</li> </ul>

Abbreviation: EDC, estimated date of conception; LMP, first day of last menstrual period.

### 9.3.4. Migraine Identification

A modified version of previously published algorithms was used to identify migraine any time before or during pregnancy ([Hoffman et al. 2019](#), [Yusuf et al. 2018](#), [Wood et al. 2021](#), [Kolodner et al. 2004](#)). The algorithm criteria are described in Table C. More information about migraine identification can be found in the protocol and SAP.

**Table C. Identification of Pregnancies with Migraine in the Present Study**

Algorithm Element	Description
Migraine codes	ICD-10-CM: G43.xx (any code nested in G43) in any position
Migraine-specific treatments	Triptans, ergots, gepants, ditans, CGRP monoclonal antibodies
Period to identify migraine codes and migraine-specific treatments	Any time before or during pregnancy (i.e., using data available during the pregnancy [EDC through pregnancy end], during the 6-month minimum continuous enrollment period prior to EDC, and in any available data > 6 months prior to EDC)
Algorithm criteria	
≥ 1 of the following: <ul style="list-style-type: none"> <li>≥ 1 IP claim for migraine AND ≥ 1 OP/ED claim for migraine at least 7 days apart within 1 year</li> <li>≥ 1 IP claim for migraine AND ≥ 1 migraine-specific treatment dispensing ≥ 7 days apart within 1 year</li> </ul>	



**Table C. Identification of Pregnancies with Migraine in the Present Study**

- $\geq 2$  OP/ED claims for migraine  $\geq 7$  days apart
- $\geq 1$  OP/ED claim for migraine AND  $\geq 1$  migraine-specific treatment dispensing  $\geq 7$  days apart
- $\geq 2$  migraine-specific treatment dispensings  $\geq 7$  days apart

Abbreviations: CGRP, calcitonin gene-related peptide; ED, emergency department; EDC, estimated date of conception; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IP, inpatient; OP, outpatient

### 9.3.5. Exposure Cohorts

There were 3 primary exposure cohorts: the Zavegepant-exposed Cohort, the Treated Comparator Cohort, and the Untreated Comparator Cohort. Because the exposure windows differ by outcome, the cohort assignments for an individual pregnancy may differ by outcome. For example, the exposure window (i.e., relevant etiologic period) for MCM was the first trimester and the exposure window for stillbirth was the full pregnancy period (Table D). Therefore, a pregnancy exposed to zavegepant in the second trimester would not have been included in the zavegepant-exposed cohort for the MCM analysis, but it would have been included in the zavegepant-exposed cohort for the stillbirth analysis. An individual pregnancy did not contribute to multiple cohorts for a single outcome.

Pregnancies exposed to both zavegepant and other cohort-defining acute migraine treatments (i.e., triptans or ditans) were removed from analyses, and any exposure that began after the occurrence of an outcome was not used to define cohort assignment for that particular outcome.

For all cohort-defining drugs (i.e., drugs that define the Zavegepant-exposed and Treated Comparator Cohorts), exposure periods for each dispensing/administration were defined using the date of dispensing or administration and the days' supply or recommended administration schedule plus 5 times the half-life of the therapy. If the exposure period overlapped with the exposure window by at least one day, the pregnancy was considered exposed (Figure A). The defined exposure window varied by study outcome, according to its relevant etiologic period (Table D).

**Table D. Timing of Exposure Assessment**

Outcome	Exposure window (relevant etiologic period)
MCM	30 days prior to EDC through end of the first trimester
Spontaneous abortion	30 days prior to EDC through 20 weeks' gestation
Pre-eclampsia	30 days prior to EDC through date of pre-eclampsia or end of pregnancy
Eclampsia	30 days prior to EDC through date of eclampsia or end of pregnancy
Gestational diabetes	30 days prior to EDC through date of gestational diabetes or end of pregnancy

**Table D. Timing of Exposure Assessment**

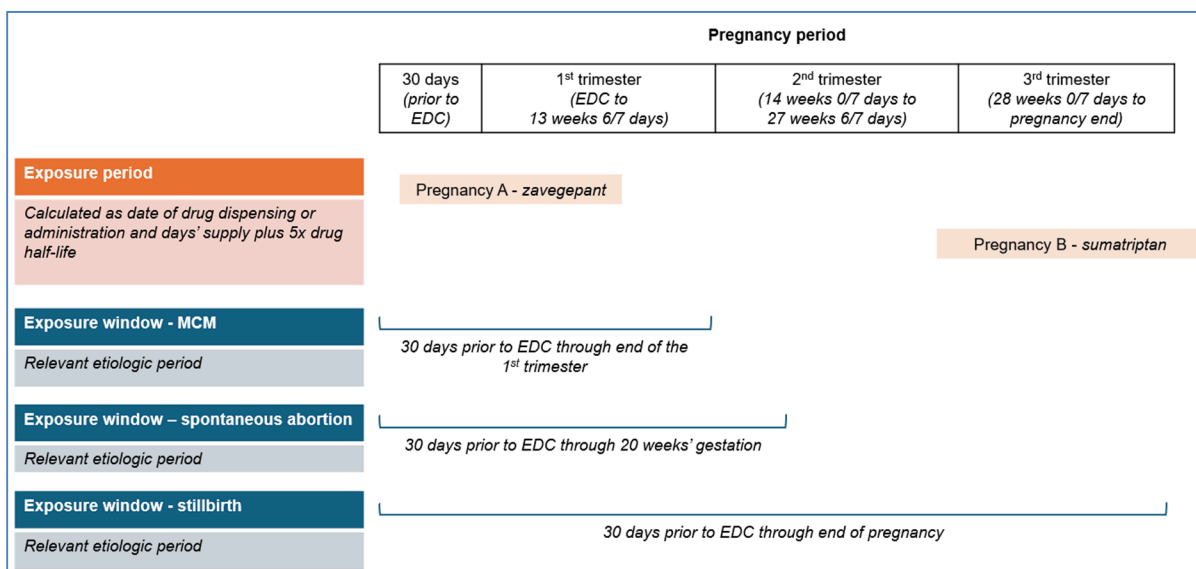
Outcome	Exposure window (relevant etiologic period)
Gestational hypertension	30 days prior to EDC through date of gestational hypertension or end of pregnancy
Stillbirth	30 days prior to EDC through end of pregnancy
Preterm birth	30 days prior to EDC through end of pregnancy
SGA	30 days prior to EDC through end of pregnancy

Abbreviations: MCM, major congenital malformation; SGA, small for gestational age birth.

Figure A describes 2 example pregnancies (A and B) and exposure windows for 3 selected outcomes (MCM, spontaneous abortion, and stillbirth). Pregnancy A has a zavegepant exposure period beginning in the month prior to EDC and ending mid-way through the first trimester. For the MCM analysis, where the exposure window (i.e., relevant etiologic period) is the 30 days prior to EDC through the end of the first trimester, pregnancy A would be classified into the Zavegepant-exposed Cohort because the zavegepant exposure period overlaps with the MCM exposure window. Applying the same logic, pregnancy A would be classified into the Zavegepant-exposed Cohort for the spontaneous abortion and stillbirth analyses as well.

Pregnancy B has a sumatriptan exposure period starting near the end of the second trimester and ending after delivery. This exposure period overlaps with the stillbirth exposure window but does not overlap with the MCM or spontaneous abortion exposure windows. Therefore, this pregnancy would be classified into the Untreated Comparator Cohort for the MCM and spontaneous abortion analyses, and into the Treated Comparator Cohort for the stillbirth analysis.

**Figure A. Exposure Classification**



### 9.3.5.1. Zavegepant-exposed Cohort

The Zavegepant-exposed Cohort included eligible pregnancies that met the following criteria:

1.  $\geq 1$  exposure period for zavegepant that overlapped with the relevant exposure window (Table D).
2. No exposure period for triptans or ditans that overlapped with the relevant exposure window (Table D)
3. Migraine, based on the criteria summarized in Table C

### 9.3.5.2. Treated Comparator Cohort

The Treated Comparator Cohort included eligible pregnancies that met the following criteria:

1.  $\geq 1$  exposure period for a medication indicated for the acute treatment of migraine (i.e., triptans or ditans) that overlapped with the relevant exposure window (Table D)
2. No exposure period for zavegepant that overlapped with the relevant exposure window (Table D)
3. Migraine, based on the criteria summarized in Table C

### 9.3.5.3. Untreated Comparator Cohort

The Untreated Comparator Cohort included eligible pregnancies that met the following criteria:

1. No exposure periods for zavegepant, triptans, or ditans, that overlapped with the relevant exposure window (Table D)
2. Migraine, based on the criteria summarized in Table C

### 9.3.5.4. Baseline Period

All covariates, including continuous health plan enrollment with medical and pharmacy benefits, were assessed during the 6-month period before and including the EDC.

### 9.3.5.5. Follow-up

Pregnancy outcomes were identified from EDC through the earliest of disenrollment from the health plan, the end of the study period, or 42 days post-pregnancy end date. Each infant was followed from birth to 12 months of age, or the earliest of death, disenrollment from the health plan, or the end of the study period.

## 9.4. Variables

Most study variables were sourced from the claims data, with the exception of race and ethnicity, which Optum generated by a combination of self-report, modeling, census data, and a variety of other individual-level and population-level data sources.

### 9.4.1. Exposures

Exposure periods for migraine medications were defined for each pregnancy using the date of dispensing or administration as the start of exposure and the days' supply or recommended administration schedule plus 5 times the half-life of the therapy as the length

of exposure. If an exposure period for a migraine medication overlapped with an exposure window, the pregnancy was considered exposed. The defined exposure window varied by study outcome, according to its relevant etiologic period ([Table D](#)).

#### 9.4.1.1. Zavegepant

Zavegepant dispensings were identified by the following National Drug Codes (NDC).

- 0069-3500-01 Zavzpret 10 mg spray
- 0069-3500-02 Zavzpret 10 mg spray

#### 9.4.1.2. Comparator Migraine Treatments

The acute migraine treatments used to identify the Treated Comparator Cohort are listed below.

- Triptans: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
- Ditans: lasmiditan

A full list of NDC and HCPCS codes for these treatments can be found in [Appendix A](#).

#### 9.4.2. Outcomes

The primary outcome was MCM and the secondary outcomes were spontaneous abortion, pregnancy complications (pre-eclampsia, eclampsia, gestational diabetes, gestational hypertension), stillbirth, preterm birth, and SGA. All study outcomes were identified via claims-based algorithms using ICD-10-CM diagnosis and procedure codes, CPT® procedure codes, and HCPCS procedure codes on facility and physician claims. Denominators and outcome assessment windows can be found in Table E. Outcome code lists can be found in the protocol and the SAP.

**Table E. Denominator and Outcome Assessment Window for All Outcomes**

Outcome	Denominator	Outcome Ascertainment Window*
MCM	All linked livebirths	Birth through 365 days after birth
Spontaneous abortion	All pregnancies	EDC through 19 weeks 6/7 days of gestation
Pre-eclampsia	All pregnancies	20 weeks of gestation through 42 days after the end of pregnancy
Eclampsia	All pregnancies	20 weeks of gestation through 42 days after the end of pregnancy
Gestational diabetes	All pregnancies	20 weeks of gestation through 42 days after the end of pregnancy
Gestational hypertension	All pregnancies	20 weeks of gestation through 42 days after the end of pregnancy

**Table E. Denominator and Outcome Assessment Window for All Outcomes**

Outcome	Denominator	Outcome Ascertainment Window*
Stillbirth	All pregnancies	20 weeks of gestation through end of the pregnancy
Preterm birth	All livebirths	< 37 completed weeks of gestation  Algorithm A (sensitivity analysis): within 0-30 days after pregnancy end date  Algorithm B (primary): Maternal codes within 0-7 days before pregnancy end; infant codes within 0-30 days after pregnancy end date
SGA	All linked livebirths	From date of delivery through 30 days after delivery

\*The window for outcome ascertainment also ended at disenrollment or end of the study period.

#### 9.4.2.1. MCM

Two algorithms were used to identify MCMs in the interim report. The sensitive algorithm is most relevant for the final study report because it will be used to identify potential cases for medical record validation. This algorithm aims to reduce false negatives by requiring only 1 MCM code. It is associated with a high proportion of false positives (positive predictive value [PPV] 44%; [Chomistek et al. 2023](#)) and is likely to overestimate prevalence. The specific algorithm, which requires at least 2 codes, is most relevant for the interim reports. However, it is also associated with false positives (PPV 68%; [Chomistek et al. 2023](#)).

The sensitive algorithm was defined as at least 1 MCM diagnosis code at any site in any position on the infant record, while the specific algorithm required at least 2 MCM diagnosis codes at least 30 days apart at any site in any position on the infant record. Codes were identified from birth to 365 days after birth, or the earliest of death, disenrollment from the health plan, or end of the study period.

#### 9.4.2.2. Spontaneous Abortion

Spontaneous abortion was defined as pregnancy loss at < 20 weeks of gestation and was identified on maternal claims during the outcome assessment window as ≥1 spontaneous abortion diagnosis and/or procedure code.

#### 9.4.2.3. Pregnancy Complications

Pregnancy complications included pre-eclampsia, eclampsia, gestational diabetes, and gestational hypertension. All pregnancy complications were identified on maternal claims at ≥ 20 weeks of gestation based on ICD-10 diagnosis codes and CPT codes.

#### 9.4.2.3.1. Pre-eclampsia

Pre-eclampsia was defined by the American College of Obstetricians and Gynecologists (ACOG) as proteinuria with either 1) systolic blood pressure of  $\geq 140$  mmHg or diastolic blood pressure of  $\geq 90$  mmHg after 20 weeks of gestation in a patient with previously normal blood pressure, or 2) systolic blood pressure of  $\geq 160$  mmHg or diastolic blood pressure of  $\geq 110$  mmHg; or in the absence of proteinuria, a new-onset hypertension with thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or unexplained new headaches unresponsive to medication and not accounted for by alternative diagnoses or visual symptoms (ACOG 2020). Cases of pre-eclampsia were identified on maternal claims as  $\geq 1$  pre-eclampsia ICD-10-CM diagnosis code.

#### 9.4.2.3.2. Eclampsia

Eclampsia was defined as new-onset hypertensive tonic-clonic, focal, or multifocal seizures during pregnancy (ACOG 2020). Cases of eclampsia were identified on maternal claims as  $\geq 1$  eclampsia ICD-10-CM diagnosis code.

#### 9.4.2.3.3. Gestational Diabetes

Gestational diabetes was defined by ACOG as a positive 50-g 1-hour glucose tolerance test administered between 24 and 28 weeks of pregnancy followed by a positive 100-g 3-hour oral glucose tolerance test (ACOG 2018). Cases of gestational diabetes were identified using the following algorithm:

- $\geq 2$  maternal outpatient diabetes/gestational diabetes diagnosis codes that occurred on different dates

Plus 1 of the following:

- A CPT code for a glucose tolerance test during the outcome assessment window OR
- A diagnosis code for gestational diabetes during the outcome assessment window plus no anti-diabetic drug dispensing or code for pre-gestational diabetes (i.e., diabetes before pregnancy start) between 365 and 180 days prior to the date of delivery or pregnancy outcome.

#### 9.4.2.3.4. Gestational Hypertension

Gestational hypertension was defined by ACOG as systolic blood pressure  $\geq 140$  mmHg or diastolic blood pressure  $\geq 90$  mmHg after 20 weeks gestation in a patient with previously normal blood pressure (ACOG 2020). Cases of gestational hypertension were identified on maternal claims at  $\geq 20$  weeks of gestation as  $\geq 1$  gestational hypertension ICD-10-CM diagnosis code.

#### 9.4.2.4. Stillbirth

Stillbirth was defined as fetal death at  $\geq 20$  weeks of gestation. Cases of stillbirth were identified by  $\geq 1$  maternal stillbirth diagnosis/procedure code or  $\geq 1$  livebirth and stillbirth diagnosis/procedure code occurring at or after 20 weeks of gestation.

#### 9.4.2.5. Preterm Birth

Preterm birth was defined as a livebirth occurring at < 37 gestational weeks. Three algorithms were used.

- Algorithm A (sensitivity analysis):  $\geq 1$  maternal or infant diagnosis code for preterm birth, low birth weight, or specific conditions more common in preterm infants identified within 0-30 days of delivery ([Eworuke et al., 2012](#))
- Algorithm B (primary):  $\geq 1$  maternal or infant diagnosis code for gestational age in weeks corresponding to < 37 weeks at birth identified within the last 7 days of pregnancy on maternal claims or within 0-30 days of delivery on infant claims ([Andrade et al., 2013](#))
- Algorithm C (sensitivity analysis): met the criteria for either Algorithm A or B

#### 9.4.2.6. SGA

SGA was defined as a liveborn infant with birth weight below the 10th percentile for gestational age at birth. It was identified on maternal and infant claims as  $\geq 1$  maternal or infant diagnosis code within 0-30 days of delivery.

#### 9.4.3. Covariates

Select covariates were identified in this interim report. Full definitions and code lists can be found in the protocol and SAP.

- Demographic and general characteristics:
  - Age at EDC
  - Race
  - Ethnicity
  - Geographic region at EDC
  - Calendar year of EDC
  - Years of continuous enrollment prior to EDC
- History of medical conditions:
  - Alcohol misuse
  - Chronic kidney disease
  - Diabetes
  - Drug misuse
  - Hypertension
  - Obesity
  - Smoking
  - Thyroid disease
- Medications:
  - Anticoagulants
  - Antihypertensive medications
  - Antiplatelet agents
  - Antithyroid medications
  - Insulin
  - Lipid-lowering drugs
  - Oral antidiabetics



- Preventive migraine drugs
- Acute migraine drugs

## 9.5. Data Sources and Measurement

### 9.5.1. The Optum Research Database (ORD)

The patients included in this study were drawn from the ORD, a proprietary research database containing eligibility, pharmacy claims, and medical claims data from a large US health plan affiliated with Optum. The individuals covered by this health plan are geographically diverse across the US. For 2023, data are available for approximately 11.0 million individuals with medical and pharmacy coverage. Optum Epidemiology research activities utilize de-identified data from the research database. In limited instances, patient identifiers may be accessed where applicable law allows the use of patient-identifiable data, and when the study obtains appropriate approvals for accessing data that are not de-identified. Further information about the ORD can be found in the protocol and SAP.

### 9.5.2. The Optum Dynamic Assessment of Pregnancies and Infants (DAPI)

This study used Optum DAPI, a proprietary process that includes a set of capabilities and established algorithms that is applied to the ORD claims data to identify pregnancies, trimesters, and pregnancy outcomes, and to link mothers' and infants' data in an ongoing manner ([Bertoia et al. 2022](#)). The algorithms are based on a combination of validated algorithms as reported in the literature and clinical input. Mother and infant records are linked through the presence of a common unique family insurance ID. This number is used by health plans to identify all members of a family who are covered by the same insurance plan for the purposes of defining coverage, payment, and reimbursement, providing assurance that mother-infant pairs identified in this manner are accurate. In addition, claims relating to the delivery must be within 7 days of the infant's birthdate (or 32 days for multiples) for a mother-infant pair to be linked. In comparison with the broader US population, the females of child-bearing age who are included in the ORD (and DAPI) tend to be healthier, reflecting the underlying population of the commercial insurance enrollees, and likely have an age distribution more skewed toward older age, reflecting the age distribution of females within the work force. In 2022, there were approximately 170,000 pregnancies identified each year within the database, and historically 80% of pregnancies (with observed outcomes) result in livebirths, 85% of which can be linked to an infant within the database. Further information about DAPI can be found in the protocol and SAP.

## 9.6. Bias

Not applicable for this interim report.

## 9.7. Study Size

The goal of the interim reports is to assess accrual. The study aims to accrue 884 zavegepant-exposed pregnancies and 2,652 pregnancies in each comparator cohort to detect a risk ratio of 2.0 for the primary outcome MCM with 80% power. Estimated power will be greater for all secondary outcomes except stillbirth. Sample size calculations can be found in [Section 9.5 of the protocol](#).



## 9.8. Data Transformation

Detailed methodology for data transformations, particularly complex transformations (e.g., many raw variables used to derive an analytic variable), are documented in the SAP, which is dated, filed, and maintained by the sponsor.

## 9.9. Statistical Methods

The flow of pregnancies into the 3 study cohorts, including the number of accrued pregnancies meeting each of the eligibility criteria, was described. Accrual and covariates were characterized for a first trimester exposure window (30 days prior to EDC through end of first trimester) and a full pregnancy exposure window (30 days prior to EDC through end of pregnancy). Each study cohort was described with respect to the covariates listed in [Section 9.4.3](#) in both exposure windows. Continuous variables were described using the median and interquartile range (reported as 25th [Q1], 75th [Q3] percentiles), while binary and categorical variables were summarized with counts and percentages. Claims-identified outcome counts were calculated to assess whether the prevalence estimates incorporated into the power calculation hold. No comparative analyses were conducted in this interim report. All analyses were conducted using Statistical Analysis System (SAS) version 9.4 (SAS Institute Inc., Cary, NC) and SAS Enterprise Guide 8.2.

## 9.10. Quality Control

The conduct and reporting of this study followed Optum Epidemiology's Standard Operating Procedures (SOPs) that are consistent with the following:

- International Society for Pharmacoepidemiology (ISPE)'s Guidelines for Good Pharmacoepidemiology Practices (GPP) ([ISPE 2015](#))
- FDA's Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data ([FDA 2013](#))
- FDA's Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products ([FDA 2024](#))
- FDA draft guidance document Postapproval Pregnancy Safety Studies Guidance for Industry ([FDA 2019](#))

The SOPs in place at Optum prescribe that processes and deliverables are documented, reviewed, and validated in sufficient detail to allow for subsequent re-examination or replication. Further information about quality control and the validity of the ORD for epidemiologic research can be found in [section 9.8 of the protocol](#).

## 9.11. Protection of Human Subjects

### Subject information and consent

Not applicable.

### Institutional Review Board (IRB)

This study protocol was approved by the Biomedical Research Alliance of New York IRB (BRANY IRB), and a waiver of consent was obtained.

### Ethical conduct of the study

The study was conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value and rigor and followed generally accepted research practices described in the GPP issued by ISPE ([ISPE 2015](#)), and the European Medicines Agency, ENCePP Guide on Methodological Standards in Pharmacoepidemiology ([ENCEPP 2023](#)).

The conduct and reporting of this study follows Optum Epidemiology's SOPs that are consistent with the ISPE's GPP ([ISPE 2015](#)).

## 10. RESULTS

[Table set 1](#) describes the flow of patients into the study cohorts. After applying inclusion and exclusion criteria, there were 3,795 eligible pregnancies with migraine based on the first trimester exposure window ([Interim Table 1a](#)). Only 1 pregnancy was exposed to zavegepant. There were 958 pregnancies and 276 linked infants in the Treated Comparator Cohort and 2,836 pregnancies and 708 linked infants in the Untreated Comparator Cohort. The numbers of accrued pregnancies were similar for the full pregnancy exposure window ([Interim Table 1b](#)). Of 3,790 eligible pregnancies, 1 pregnancy was exposed to zavegepant, there were 1,058 pregnancies and 318 linked infants in the Treated Comparator Cohort, and there were 2,731 pregnancies and 664 linked infants in the Untreated Comparator Cohort.

[Table set 2](#) shows the characteristics of the final analytic sample by study cohort. Most patients were in their late twenties or early to mid-thirties ([Interim Table 2a](#)). Obesity was the most prevalent medical condition among those evaluated, followed by thyroid disease. The most common medications dispensed during baseline were preventive and acute migraine medications, and greater proportions of the Treated Comparator Cohort had dispensings compared to the Untreated Comparator Cohort ([Interim Table 2b](#)). Otherwise, characteristics were similar in the first trimester and full pregnancy exposure windows.

[Table 3](#) shows counts of pregnancy and infant outcomes by study cohort. As defined in [Table D](#), each outcome had a specific exposure window that corresponded with the outcome's relevant etiologic period. For example, the MCM exposure window was the first trimester, and the stillbirth exposure window was the full pregnancy period. Therefore, each outcome had a different denominator.

There were no maternal or infant outcomes in the Zavegepant-exposed cohort. In the Treated Comparator Cohort, 18.1% of pregnancies had codes for spontaneous abortion, 0.2% stillbirth, 2.2% gestational diabetes, 9.3% gestational hypertension, 5.4% pre-eclampsia, and 0.0% eclampsia. Among infants, 34.4% met the sensitive MCM algorithm criteria and 13.4% met the specific MCM algorithm criteria. The number of infants classified as preterm birth varied by algorithm (17.4% to 22.3%) and 11.3% of infants had SGA codes.

Outcome percentages in the Untreated Comparator Cohort were similar to the Treated Comparator Cohort, though slightly lower for gestational hypertension (5.9%), MCMs (31.6% for the sensitive algorithm and 10.6% for the specific algorithm), and preterm birth (13.5 to 18.6%).

## 11. DISCUSSION

### 11.1. Key Results

In the 20 months since FDA approval, only 1 in 3,795 eligible pregnancies with migraine was exposed to zavegepant. The low uptake is likely because zavegepant is in a higher tier in the formulary compared to other acute migraine medications, and therefore less used. In the protocol, the sample size calculation indicated that 884 zavegepant-exposed pregnancies were necessary to detect a risk ratio of 2.0 for MCMs with 80% power. Analyses of smaller sample sizes would be underpowered to detect a risk ratio of 2.0 but may still be sufficiently powered to detect or rule out larger exposure effects. Smaller sample sizes may also be adequately powered for some secondary outcomes. Accrual of zavegepant-exposed pregnancies in the ORD will continue to be assessed on an annual basis.

### 11.2. Limitations

With only 1 exposed patient, the study research question cannot be assessed at this time.

While claims data are extremely valuable for pharmacoepidemiology research, all claims databases have certain inherent limitations because the claims are collected for the purpose of payment, not research. Presence of a claim for a filled prescription does not indicate that the medication was consumed or that it was taken as prescribed. Similarly, absence of a claim for a filled prescription does not preclude the possibility of exposure to a medication. Medications filled over-the-counter, provided as samples by a physician, or received during an inpatient hospital stay will often not be observed in the claims data. Presence of a diagnosis code is not positive presence of disease, as the diagnosis code may be incorrectly coded or included as rule-out criterion rather than actual disease.

### 11.3. Interpretation

Most pregnancies were of unknown race and ethnicity, and Hispanic ethnicity was included in both the race and ethnicity variables. This occurred because the sourcing of race and ethnicity data in the ORD recently changed from imputed to self-report with the long-term goal of improved data quality. As data processing progresses, the percentage of pregnancies with unknown race and ethnicity should be reduced in future interim reports and all information on ethnicity will be included in the ethnicity variable.

For some pregnancy and infant outcomes, the observed prevalence differed from national estimates derived from the literature. The observed prevalence of stillbirth (0.1-0.2%) was lower than expected and the observed prevalence of preterm birth (13.5-22.3%) and MCM (10.6-34.4%) was higher. National estimates indicate that 0.6% of pregnancies end in stillbirth ([CDC 2025](#)), while 10.4% of live births were preterm births (CDC 2025) and 3% of infants were born with major congenital malformations (CDC 2025).

Algorithms for MCMs were intentionally sensitive to capture all possible cases, potentially including minor congenital malformations. Both MCM algorithms are associated with false positives (PPV 44-68%; [Chomistek et al. 2023](#)). Validation via medical record review in the final study report will provide a better estimate of the prevalence of MCMs in this study population.

#### **11.4. Generalizability**

Not applicable for this interim report.

#### **12. OTHER INFORMATION**

Not applicable for this interim report.

#### **13. CONCLUSIONS**

Overall, this interim report shows that one pregnancy was exposed to zavegepant in the database during the initial period of accrual. Future interim reports will continue to monitor accrual to determine whether the sample size is on track to meet projections for the final comparative analyses.

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**Interim Table 1a. Attrition Table for First Trimester Exposure Window, Optum Research Database**

	N	N removed
Pregnancies with EDC between 9 March 2023 – 31 October 2024	186,441	
Pregnancies with migraine	4,875	181,566
Pregnancies with migraine aged 15-50	4,858	17
Pregnancies with migraine aged 15-50 with at least 6 months of continuous medical and pharmacy enrollment	4,253	605
Pregnancies with migraine aged 15-50 with at least 6 months of continuous medical and pharmacy enrollment and no other CGRP exposure	3,795	458
Zavegepant-exposed cohort	1	
Linked infants <sup>a</sup>	0	
Treated comparator cohort	958	
Linked infants	276	
Untreated comparator cohort	2,836	
Linked infants	708	

Abbreviation: CGRP, calcitonin gene-related peptide; EDC, estimated date of conception  
a There is no linked infant because this pregnancy was ongoing at the time of the data pull

**Interim Table 1b. Attrition Table for Full Pregnancy Exposure Window, Optum Research Database**

	N	N removed
Pregnancies with EDC between 9 March 2023 – 31 October 2024	186,441	
Pregnancies with migraine	4,875	181,566
Pregnancies with migraine aged 15-50	4,858	17
Pregnancies with migraine aged 15-50 with at least 6 months of continuous medical and pharmacy enrollment	4,253	605
Pregnancies with migraine aged 15-50 with at least 6 months of continuous medical and pharmacy enrollment and no other CGRP exposure	3,790	463
Zavegepant-exposed cohort	1	
Linked infants <sup>a</sup>	0	
Treated comparator cohort	1,058	
Linked infants	318	
Untreated comparator cohort	2,731	
Linked infants	664	

Abbreviation: CGRP, calcitonin gene-related peptide; EDC, estimated date of conception  
a There is no linked infant because this pregnancy was ongoing at the time of the data pull



**Interim Table 2a. Characteristics by Study Cohort for First Trimester Exposure Window, Optum Research Database, 09 March 2023 – 31 October 2024**

	<b>Zavegepant Cohort N = 1</b>	<b>Treated Comparator Cohort N = 958</b>	<b>Untreated Comparator Cohort N = 2,836</b>
Demographic and general characteristics <sup>a</sup>			
Median age at EDC (Q1, Q3)	29 (29, 29)	33 (29, 36)	31 (28, 35)
Age 15-34 years N (%)	1 (100%)	594 (62.0%)	2,053 (72.4%)
Age ≥ 35 years N (%)	0 (0.0%)	364 (38.0%)	783 (27.6%)
Race N (%)			
Asian	0 (0.0%)	5 (0.5%)	26 (0.9%)
Black	0 (0.0%)	14 (1.5%)	68 (2.4%)
Hispanic	0 (0.0%)	3 (0.3%)	3 (0.1%)
White	0 (0.0%)	182 (19.0%)	507 (17.9%)
Other/multiple/unknown	1 (100%)	754 (78.7%)	2,232 (78.7%)
Ethnicity N (%)			
Hispanic or Latino	0 (0.0%)	25 (2.6%)	67 (2.4%)
Not Hispanic or Latino	0 (0.0%)	195 (20.4%)	607 (21.4%)
Unknown	1 (100%)	738 (77.0%)	2,162 (76.2%)
Geographic region, N (%)			
Northeast	0 (0.0%)	109 (11.4%)	344 (12.1%)
Midwest	1 (100%)	368 (38.4%)	854 (30.1%)
South	0 (0.0%)	312 (32.6%)	1,146 (40.4%)
West	0 (0.0%)	169 (17.6%)	488 (17.2%)
Unknown	0 (0.0%)	0 (0.0%)	4 (0.1%)
Year of EDC N (%)			
2023	0 (0.0%)	571 (59.6%)	1,509 (53.2%)
2024	1 (100%)	387 (40.4%)	1,327 (46.8%)
Median years of continuous health plan enrollment (Q1, Q3)	2 (2, 2)	3 (2, 5)	3 (2, 5)
< 1 year N (%)	0 (0.0%)	18 (1.9%)	34 (1.2%)
1-<3 years N (%)	1 (100%)	406 (42.4%)	1,335 (47.1%)
3-<5 years N (%)	0 (0.0%)	258 (26.9%)	768 (27.1%)
≥ 5 years N (%)	0 (0.0%)	276 (28.8%)	699 (24.6%)
History of medical conditions N (%) <sup>b</sup>			
Alcohol misuse	0 (0.0%)	0 (0.0%)	1 (0.0%)
Chronic kidney disease	0 (0.0%)	2 (0.2%)	6 (0.2%)
Diabetes	0 (0.0%)	21 (2.2%)	55 (1.9%)
Drug misuse	0 (0.0%)	6 (0.6%)	18 (0.6%)
Hypertension	0 (0.0%)	46 (4.8%)	186 (6.6%)
Obesity	0 (0.0%)	146 (15.2%)	567 (20.0%)
Smoking	0 (0.0%)	26 (2.7%)	93 (3.3%)
Thyroid disease	0 (0.0%)	92 (9.6%)	316 (11.1%)
Medications N (%) <sup>b</sup>			
Anticoagulants	0 (0.0%)	24 (2.5%)	65 (2.3%)
Antihypertensive medications	0 (0.0%)	28 (2.9%)	86 (3.0%)
Antiplatelet agents	0 (0.0%)	8 (0.8%)	21 (0.7%)
Antithyroid medications	0 (0.0%)	0 (0.0%)	13 (0.5%)
Insulin	0 (0.0%)	7 (0.7%)	20 (0.7%)

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**Interim Table 2a. Characteristics by Study Cohort for First Trimester Exposure Window, Optum Research Database, 09 March 2023 – 31 October 2024**

	<b>Zavegepant Cohort N = 1</b>	<b>Treated Comparator Cohort N = 958</b>	<b>Untreated Comparator Cohort N = 2,836</b>
Lipid-lowering drugs	0 (0.0%)	11 (1.1%)	50 (1.8%)
Oral antidiabetics	0 (0.0%)	57 (5.9%)	178 (6.3%)
Preventive migraine medications	1 (100%)	430 (44.9%)	1,048 (37.0%)
Acute migraine medications	0 (0.0%)	873 (91.1%)	1,084 (38.2%)

Abbreviations: EDC, estimated date of conception

a Assessed at EDC

b Assessed 6 months before and including EDC

**Interim Table 2b. Characteristics by Study Cohort for Full Pregnancy Exposure Window, Optum Research Database, 09 March 2023 – 31 October 2024**

	<b>Zavegepant Cohort N = 1</b>	<b>Treated Comparator Cohort N = 1,058</b>	<b>Untreated Comparator Cohort N = 2,731</b>
Demographic and general characteristics <sup>a</sup>			
Median age at EDC (Q1, Q3)	29 (29, 29)	33 (29, 36)	31 (28, 35)
Age 15-34 years N (%)	1 (100%)	659 (62.3%)	1,985 (72.7%)
Age ≥ 35 years N (%)	0 (0.0%)	399 (37.7%)	746 (27.3%)
Race N (%)			
Asian	0 (0.0%)	7 (0.7%)	24 (0.9%)
Black	0 (0.0%)	15 (1.4%)	67 (2.5%)
Hispanic	0 (0.0%)	3 (0.3%)	3 (0.1%)
White	0 (0.0%)	195 (18.4%)	493 (18.1%)
Other/multiple/unknown	1 (100%)	838 (79.2%)	2,144 (78.5%)
Ethnicity N (%)			
Hispanic or Latino	0 (0.0%)	28 (2.6%)	64 (2.3%)
Not Hispanic or Latino	0 (0.0%)	214 (20.2%)	588 (21.5%)
Unknown	1 (100%)	816 (77.1%)	2,079 (76.1%)
Geographic region, N (%)			
Northeast	0 (0.0%)	118 (11.2%)	334 (12.2%)
Midwest	1 (100%)	405 (38.3%)	816 (29.9%)
South	0 (0.0%)	344 (32.5%)	1,111 (40.7%)
West	0 (0.0%)	191 (18.1%)	466 (17.1%)
Unknown	0 (0.0%)	0 (0.0%)	4 (0.1%)
Year of EDC N (%)			
2023	0 (0.0%)	638 (60.3%)	1,438 (52.7%)
2024	1 (100%)	420 (39.7%)	1,293 (47.3%)
Median years of continuous health plan enrollment (Q1, Q3)	2 (2, 2)	3 (2, 5)	3 (2, 5)
< 1 year N (%)	0 (0.0%)	18 (1.7%)	34 (1.2%)
1-<3 years N (%)	1 (100%)	454 (42.9%)	1,286 (47.1%)
3-<5 years N (%)	0 (0.0%)	284 (26.8%)	741 (27.1%)
≥ 5 years N (%)	0 (0.0%)	302 (28.5%)	670 (24.5%)
History of medical conditions N (%) <sup>b</sup>			
Alcohol misuse	0 (0.0%)	0 (0.0%)	1 (0.0%)
Chronic kidney disease	0 (0.0%)	3 (0.3%)	5 (0.2%)
Diabetes	0 (0.0%)	24 (2.3%)	52 (1.9%)
Drug misuse	0 (0.0%)	6 (0.6%)	18 (0.7%)
Hypertension	0 (0.0%)	51 (4.8%)	181 (6.6%)
Obesity	0 (0.0%)	165 (15.6%)	548 (20.1%)
Smoking	0 (0.0%)	31 (2.9%)	88 (3.2%)
Thyroid disease	0 (0.0%)	100 (9.5%)	308 (11.3%)
Medications N (%) <sup>b</sup>			
Anticoagulants	0 (0.0%)	27 (2.6%)	62 (2.3%)
Antihypertensive medications	0 (0.0%)	33 (3.1%)	81 (3.0%)
Antiplatelet agents	0 (0.0%)	9 (0.9%)	20 (0.7%)
Antithyroid medications	0 (0.0%)	0 (0.0%)	13 (0.5%)
Insulin	0 (0.0%)	8 (0.8%)	19 (0.7%)

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**Interim Table 2b. Characteristics by Study Cohort for Full Pregnancy Exposure Window, Optum Research Database, 09 March 2023 – 31 October 2024**

	<b>Zavegepant Cohort N = 1</b>	<b>Treated Comparator Cohort N = 1,058</b>	<b>Untreated Comparator Cohort N = 2,731</b>
Lipid-lowering drugs	0 (0.0%)	14 (1.3%)	47 (1.7%)
Oral antidiabetics	0 (0.0%)	67 (6.3%)	168 (6.2%)
Preventive migraine medications	1 (100%)	466 (44.0%)	1,010 (37.0%)
Acute migraine medications	0 (0.0%)	914 (86.4%)	1,041 (38.1%)

Abbreviations: EDC, estimated date of conception

a Assessed at EDC

b Assessed 6 months before and including EDC

**Interim Table 3. Counts of Outcomes by Study Cohort, Optum Research Database, 09 March 2023 – 31 October 2024**

	Zavegepant Cohort		Treated Comparator Cohort		Untreated Comparator Cohort	
	Denominator	Event	Denominator	Event	Denominator	Event
Pregnancy outcomes						
Spontaneous abortion <sup>a</sup>	1	0 (0.0%)	1,007	182 (18.1%)	2,787	494 (17.7%)
Stillbirth <sup>b</sup>	1	0 (0.0%)	1,058	2 (0.2%)	2,731	4 (0.1%)
Gestational diabetes <sup>b</sup>	1	0 (0.0%)	1,058	23 (2.2%)	2,731	49 (1.8%)
Gestational hypertension <sup>b</sup>	1	0 (0.0%)	1,058	98 (9.3%)	2,731	160 (5.9%)
Pre-eclampsia <sup>b</sup>	1	0 (0.0%)	1,058	57 (5.4%)	2,731	116 (4.2%)
Eclampsia <sup>b</sup>	1	0 (0.0%)	1,058	0 (0.0%)	2,731	4 (0.1%)
Infant outcomes						
Major congenital malformations <sup>c</sup>						
Sensitive algorithm	0	N/A	276	95 (34.4%)	708	224 (31.6%)
Specific algorithm	0	N/A	276	37 (13.4%)	708	75 (10.6%)
Preterm birth <sup>d</sup>						
Algorithm A (sensitivity)	0	N/A	391	75 (19.2%)	839	140 (16.7%)
Algorithm B (primary)	0	N/A	391	68 (17.4%)	839	113 (13.5%)
Algorithm C (sensitivity)	0	N/A	391	87 (22.3%)	839	156 (18.6%)
Small for gestational age <sup>e</sup>	0	N/A	318	36 (11.3%)	664	77 (11.6%)

<sup>a</sup> Denominator is all pregnancies that were exposed or unexposed through 19 weeks 6/7 days of gestation

<sup>b</sup> Denominator is all pregnancies in the full pregnancy exposure cohorts

<sup>c</sup> Denominator is all linked live births in the first trimester exposure cohorts

<sup>d</sup> Denominator is all livebirths in the full pregnancy exposure cohorts

<sup>e</sup> Denominator is all linked livebirths in the full pregnancy exposure cohorts

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## 16. APPENDIX A: CODE LIST FOR DRUGS INCLUDED IN THE TREATED COMPARATOR COHORT

### Triptans:

- Almotriptan
  - NDC 10147096101 Almotriptan malate 12.5 mg tablet
  - NDC 10147096201 Almotriptan malate 6.25 mg tablet
  - NDC 00025208006 axert 6.25mg tablet
  - NDC 00025208506 axert 12.5mg tablet
  - NDC 27241004111 Almotriptan malate 6.25 mg tablet
  - NDC 27241004168 Almotriptan malate 6.25 mg tablet
  - NDC 27241004222 Almotriptan malate 12.5 mg tablet
  - NDC 27241004268 Almotriptan malate 12.5 mg tablet
  - NDC 00378524532 Almotriptan malate 6.25 mg tablet
  - NDC 00378524585 Almotriptan malate 6.25 mg tablet
  - NDC 00378524632 Almotriptan malate 12.5 mg tablet
  - NDC 00378524685 Almotriptan malate 12.5 mg tablet
  - NDC 50458021001 axert 12.5 mg tablet
  - NDC 50458021101 axert 6.25 mg tablet
  - NDC 54868552700 axert 12.5mg tablet
  - NDC 54868552701 axert 12.5mg tablet
  - NDC 00062208006 axert 6.25mg tablet
  - NDC 00062208506 axert 12.5mg tablet
  - NDC 00062208512 axert 12.5mg tablet
  - NDC 68115070506 axert 12.5mg tablet
  - NDC 00093526018 Almotriptan malate 6.25 mg tablet
  - NDC 00093526019 Almotriptan malate 6.25 mg tablet
  - NDC 00093526119 Almotriptan malate 12.5 mg tablet
  - NDC 00093526129 Almotriptan malate 12.5 mg tablet
- Eletriptan
  - NDC 16590020112 relpax 40mg tablet
  - NDC 00049233034 relpax 20mg tablet
  - NDC 00049233045 relpax 20mg tablet
  - NDC 00049233079 relpax 20 mg tablet
  - NDC 00049234005 relpax 40mg tablet
  - NDC 00049234034 relpax 40mg tablet
  - NDC 00049234034 relpax 40mg tablet
  - NDC 00049234034 relpax 40mg tablet
  - NDC 00049234034 relpax 40mg tablet
  - NDC 00049234034 relpax 40mg tablet
  - NDC 00049234045 relpax 40mg tablet
  - NDC 54868552800 relpax 40mg tablet
  - NDC 55887018712 relpax 40mg tablet
  - NDC 57866018702 relpax 40mg tablet
  - NDC 58016487701 relpax 40mg tablet
  - NDC 68115073712 relpax 40mg tablet

- Frovatriptan
  - NDC 12280028909 frova 2.5mg tablet
  - NDC 21695022209 frova 2.5mg tablet
  - NDC 35356016909 frova 2.5mg tablet
  - NDC 00378314032 frovatriptan succinate 2.5 mg tablet
  - NDC 00378314085 frovatriptan succinate 2.5 mg tablet
  - NDC 50742029909 frovatriptan succinate 2.5 mg tablet
  - NDC 58016083801 frova 2.5mg tablet
  - NDC 59075074089 frova 2.5mg tablet
  - NDC 00603371834 frovatriptan succinate 2.5 mg tablet
  - NDC 63481002509 frova 2.5mg tablet
  - NDC 68462069497 frovatriptan succinate 2.5 mg tablet
  - NDC 69238153909 frovatriptan succinate 2.5 mg
- Naratriptan
  - NDC 16714029001 naratriptan 1 mg tablet
  - NDC 16714029002 naratriptan 1 mg tablet
  - NDC 16714029101 naratriptan 2.5 mg tablet
  - NDC 16714029102 naratriptan 2.5 mg tablet
  - NDC 00173056100 amerge 1mg tablet
  - NDC 00173056200 amerge 2.5mg tablet
  - NDC 23155005419 naratriptan hcl 1 mg tablet
  - NDC 23155005519 naratriptan hcl 2.5 mg tablet
  - NDC 00378445059 naratriptan hcl 1 mg tablet
  - NDC 00378445159 naratriptan hcl 2.5 mg tablet
  - NDC 42043013000 naratriptan hcl 1 mg tablet
  - NDC 42043013009 naratriptan hcl 1 mg tablet
  - NDC 42043013100 naratriptan hcl 2.5 mg tablet
  - NDC 42043013109 naratriptan hcl 2.5 mg tablet
  - NDC 50090616200 naratriptan hcl 2.5 mg tablet
  - NDC 00054027803 naratriptan hcl 1 mg tablet
  - NDC 00054027903 naratriptan hcl 2.5 mg tablet
  - NDC 00574021409 naratriptan hcl 1 mg tablet
  - NDC 00574021509 naratriptan hcl 2.5 mg tablet
  - NDC 62756043769 naratriptan hcl 2.5 mg tablet
  - NDC 69452034160 naratriptan hcl 2.5 mg tablet
  - NDC 69452034172 naratriptan hcl 2.5 mg tablet
  - NDC 00781552737 naratriptan hcl 2.5 mg tablet
  - NDC 00093852219 naratriptan hcl 1 mg tablet
  - NDC 00093852290 naratriptan hcl 1 mg tablet
  - NDC 00093852319 naratriptan hcl 2.5 mg tablet
  - NDC 00093852390 naratriptan hcl 2.5 mg tablet
- Rizatriptan
  - NDC 16590014409 maxalt 5mg tablet
  - NDC 16590014509 maxalt mlt 5mg tab rapdis
  - NDC 21695095618 maxalt 10 mg tablet
  - NDC 23155024422 rizatriptan 5 mg tablet
  - NDC 23155024446 rizatriptan 5 mg tablet

- NDC 23155024522 rizatriptan 10 mg tablet
- NDC 23155024546 rizatriptan 10 mg tablet
- NDC 29300026831 rizatriptan 5 mg tab rapdis
- NDC 29300026881 rizatriptan 5 mg tab rapdis
- NDC 29300026891 rizatriptan 5 mg tab rapdis
- NDC 29300026931 rizatriptan 10 mg tab rapdis
- NDC 29300026981 rizatriptan 10 mg tab rapdis
- NDC 29300026991 rizatriptan 10 mg tab rapdis
- NDC 29300031621 rizatriptan 5 mg tablet
- NDC 29300031631 rizatriptan 5 mg tablet
- NDC 29300031681 rizatriptan 5 mg tablet
- NDC 29300031721 rizatriptan 10 mg tablet
- NDC 29300031731 rizatriptan 10 mg tablet
- NDC 29300031781 rizatriptan 10 mg tablet
- NDC 31722046206 rizatriptan 5 mg tablet
- NDC 31722046218 rizatriptan 5 mg tablet
- NDC 31722046306 rizatriptan 10 mg tablet
- NDC 31722046318 rizatriptan 10 mg tablet
- NDC 33342008702 rizatriptan 5 mg tablet
- NDC 33342008741 rizatriptan 5 mg tablet
- NDC 33342008745 rizatriptan 5 mg tablet
- NDC 33342008750 rizatriptan 5 mg tablet
- NDC 33342008752 rizatriptan 5 mg tablet
- NDC 33342008772 rizatriptan 5 mg tablet
- NDC 33342008802 rizatriptan 10 mg tablet
- NDC 33342008841 rizatriptan 10 mg tablet
- NDC 33342008845 rizatriptan 10 mg tablet
- NDC 33342008850 rizatriptan 10 mg tablet
- NDC 33342008852 rizatriptan 10 mg tablet
- NDC 33342008872 rizatriptan 10 mg tablet
- NDC 33342009302 rizatriptan 5 mg tab rapdis
- NDC 33342009341 rizatriptan 5 mg tab rapdis
- NDC 33342009345 rizatriptan 5 mg tab rapdis
- NDC 33342009352 rizatriptan 5 mg tab rapdis
- NDC 33342009372 rizatriptan 5 mg tab rapdis
- NDC 33342009373 rizatriptan 5 mg tab rapdis
- NDC 33342009402 rizatriptan 10 mg tab rapdis
- NDC 33342009441 rizatriptan 10 mg tab rapdis
- NDC 33342009445 rizatriptan 10 mg tab rapdis
- NDC 33342009452 rizatriptan 10 mg tab rapdis
- NDC 33342009472 rizatriptan 10 mg tab rapdis
- NDC 33342009473 rizatriptan 10 mg tab rapdis
- NDC 35356025212 maxalt 10mg tablet
- NDC 35356025218 maxalt 10 mg tablet
- NDC 35356027512 maxalt mlt 10mg tab rapdis
- NDC 00378140396 rizatriptan 5 mg tablet
- NDC 00378140496 rizatriptan 10 mg tablet
- NDC 00378370159 rizatriptan 5 mg tab rapdis
- NDC 00378370259 rizatriptan 10 mg tab rapdis

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- NDC 47335023160 rizatriptan 5 mg tablet
- NDC 47335023171 rizatriptan 5 mg tablet
- NDC 47335023260 rizatriptan 10 mg tablet
- NDC 47335023271 rizatriptan 10 mg tablet
- NDC 49884057852 rizatriptan 5 mg tablet
- NDC 49884057894 rizatriptan 5 mg tablet
- NDC 49884057952 rizatriptan 10 mg tablet
- NDC 49884057994 rizatriptan 10 mg tablet
- NDC 49884058052 rizatriptan 5 mg tab rapdis
- NDC 49884058094 rizatriptan 5 mg tab rapdis
- NDC 49884058152 rizatriptan 10 mg tab rapdis
- NDC 49884058194 rizatriptan 10 mg tab rapdis
- NDC 50090206900 rizatriptan 10 mg tablet
- NDC 50090334300 rizatriptan 10 mg tablet
- NDC 50090336700 rizatriptan 10 mg tablet
- NDC 51407067903 rizatriptan 5 mg tab rapdis
- NDC 51407067906 rizatriptan 5 mg tab rapdis
- NDC 51407067911 rizatriptan 5 mg tab rapdis
- NDC 51407067918 rizatriptan 5 mg tab rapdis
- NDC 51407067918 rizatriptan 5 mg tab rapdis
- NDC 51407068003 rizatriptan 10 mg tab rapdis
- NDC 51407068006 rizatriptan 10 mg tab rapdis
- NDC 51407068011 rizatriptan 10 mg tab rapdis
- NDC 51407068018 rizatriptan 10 mg tab rapdis
- NDC 51407068103 rizatriptan 5 mg tablet
- NDC 51407068106 rizatriptan 5 mg tablet
- NDC 51407068112 rizatriptan 5 mg tablet
- NDC 51407068118 rizatriptan 5 mg tablet
- NDC 51407068203 rizatriptan 10 mg tablet
- NDC 51407068206 rizatriptan 10 mg tablet
- NDC 51407068212 rizatriptan 10 mg tablet
- NDC 51407068218 rizatriptan 10 mg tablet
- NDC 51991035478 rizatriptan 5 mg tablet
- NDC 51991035499 rizatriptan 5 mg tablet
- NDC 51991035578 rizatriptan 10 mg tablet
- NDC 51991035599 rizatriptan 10 mg tablet
- NDC 51991036278 rizatriptan 5 mg tab rapdis
- NDC 51991036299 rizatriptan 5 mg tab rapdis
- NDC 51991036378 rizatriptan 10 mg tab rapdis
- NDC 51991036399 rizatriptan 10 mg tab rapdis
- NDC 52959078606 maxalt 10mg tablet
- NDC 54569522200 maxalt mlt 10mg tab rapdis
- NDC 54569640400 rizatriptan 10 mg tablet
- NDC 54868425100 maxalt 10mg tablet
- NDC 54868425101 maxalt 10mg tablet
- NDC 54868425102 maxalt 10mg tablet
- NDC 54868425103 maxalt 10mg tablet
- NDC 54868449900 maxalt mlt 10mg tab rapdis
- NDC 54868449901 maxalt mlt 10mg tab rapdis

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- NDC 54868449902 maxalt mlt 10 mg tab rapdis
- NDC 55887018809 maxalt mlt 10mg tab rapdis
- NDC 55887021009 maxalt 10mg tablet
- NDC 57237008563 rizatriptan 5 mg tab rapdis
- NDC 57237008734 rizatriptan 5 mg tablet
- NDC 57237008763 rizatriptan 5 mg tablet
- NDC 57237008834 rizatriptan 10 mg tablet
- NDC 57237008863 rizatriptan 10 mg tablet
- NDC 58016093800 maxalt 5mg tablet
- NDC 58016093806 maxalt 5mg tablet
- NDC 58016093830 maxalt 5mg tablet
- NDC 58016093860 maxalt 5mg tablet
- NDC 58016093890 maxalt 5mg tablet
- NDC 58016571206 maxalt 10mg tablet
- NDC 59746041404 rizatriptan 5 mg tablet
- NDC 59746041419 rizatriptan 5 mg tablet
- NDC 59746041504 rizatriptan 10 mg tablet
- NDC 59746041519 rizatriptan 10 mg tablet
- NDC 00006026601 maxalt 5 mg tablet
- NDC 00006026606 maxalt 5mg tablet
- NDC 00006026609 maxalt 5mg tablet
- NDC 00006026612 maxalt 5mg tablet
- NDC 00006026618 maxalt 5 mg tablet
- NDC 00006026701 maxalt 10 mg tablet
- NDC 00006026706 maxalt 10mg tablet
- NDC 00006026709 maxalt 10mg tablet
- NDC 00006026712 maxalt 10mg tablet
- NDC 00006026718 maxalt 10 mg tablet
- NDC 60505369801 rizatriptan 5 mg tablet
- NDC 60505369901 rizatriptan 10 mg tablet
- NDC 60505369901 rizatriptan 10 mg tablet
- NDC 60505372301 rizatriptan 5 mg tab rapdis
- NDC 60505372301 rizatriptan 5 mg tab rapdis
- NDC 60505372301 rizatriptan 5 mg tab rapdis
- NDC 60505372401 rizatriptan 10 mg tab rapdis
- NDC 60505372401 rizatriptan 10 mg tab rapdis
- NDC 60505372401 rizatriptan 10 mg tab rapdis
- NDC 61919039418 rizatriptan 5 mg tablet
- NDC 61919065612 rizatriptan 10 mg tablet
- NDC 00006380001 maxalt mlt 5mg tab rapdis
- NDC 00006380006 maxalt mlt 5mg tab rapdis
- NDC 00006380009 maxalt mlt 5mg tab rapdis
- NDC 00006380012 maxalt mlt 5mg tab rapdis
- NDC 00006380018 maxalt mlt 5 mg tab rapdis
- NDC 00006380101 maxalt mlt 10mg tab rapdis
- NDC 00006380106 maxalt mlt 10mg tab rapdis
- NDC 00006380109 maxalt mlt 10mg tab rapdis
- NDC 00006380112 maxalt mlt 10mg tab rapdis
- NDC 00006380118 maxalt mlt 10 mg tab rapdis

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- NDC 65862059903 rizatriptan 5 mg tablet
- NDC 65862059912 rizatriptan 5 mg tablet
- NDC 65862060003 rizatriptan 10 mg tablet
- NDC 65862060012 rizatriptan 10 mg tablet
- NDC 65862062503 rizatriptan 5 mg tab rapdis
- NDC 65862062503 rizatriptan 5 mg tab rapdis
- NDC 65862062512 rizatriptan 5 mg tab rapdis
- NDC 65862062590 rizatriptan 5 mg tab rapdis
- NDC 65862062603 rizatriptan 10 mg tab rapdis
- NDC 65862062612 rizatriptan 10 mg tab rapdis
- NDC 65862062690 rizatriptan 10 mg tab rapdis
- NDC 67877026106 rizatriptan 5 mg tablet
- NDC 67877026118 rizatriptan 5 mg tablet
- NDC 67877026125 rizatriptan 5 mg tablet
- NDC 67877026206 rizatriptan 10 mg tablet
- NDC 67877026218 rizatriptan 10 mg tablet
- NDC 67877026225 rizatriptan 10 mg tablet
- NDC 68071026206 maxalt 10mg tablet
- NDC 68115077906 maxalt 10mg tablet
- NDC 68462046540 rizatriptan 5 mg tablet
- NDC 68462046599 rizatriptan 5 mg tablet
- NDC 68462046640 rizatriptan 10 mg tablet
- NDC 68462046699 rizatriptan 10 mg tablet
- NDC 68462046706 rizatriptan 5 mg tab rapdis
- NDC 68462046740 rizatriptan 5 mg tab rapdis
- NDC 68462046746 rizatriptan 5 mg tab rapdis
- NDC 68462046806 rizatriptan 10 mg tab rapdis
- NDC 68462046840 rizatriptan 10 mg tab rapdis
- NDC 68462046846 rizatriptan 10 mg tab rapdis
- NDC 69097018165 rizatriptan 5 mg tablet
- NDC 69097018166 rizatriptan 5 mg tablet
- NDC 69097018265 rizatriptan 10 mg tablet
- NDC 69097018266 rizatriptan 10 mg tablet
- NDC 69097086517 rizatriptan 5 mg tablet
- NDC 69097086585 rizatriptan 5 mg tablet
- NDC 69097086617 rizatriptan 10 mg tablet
- NDC 69097086685 rizatriptan 10 mg tablet
- NDC 69452015673 rizatriptan 5 mg tab rapdis
- NDC 69452015674 rizatriptan 5 mg tab rapdis
- NDC 69452015773 rizatriptan 10 mg tab rapdis
- NDC 69452015774 rizatriptan 10 mg tab rapdis
- NDC 71205039806 rizatriptan 10 mg tab rapdis
- NDC 71205055706 rizatriptan 10 mg tab rapdis
- NDC 71205064412 rizatriptan 10 mg tablet
- NDC 71335135204 rizatriptan 10 mg tablet
- NDC 71335135206 rizatriptan 10 mg tablet
- NDC 72189012618 rizatriptan 5 mg tablet
- NDC 72189025812 rizatriptan 10 mg tablet
- NDC 72189031618 rizatriptan 5 mg tablet

- NDC 72189034109 rizatriptan 10 mg tab rapdis
- NDC 72189044718 rizatriptan 10 mg tablet
- NDC 72189060918 rizatriptan 10 mg tab rapdis
- NDC 76282046206 rizatriptan 5 mg tablet
- NDC 76282046218 rizatriptan 5 mg tablet
- NDC 76282046306 rizatriptan 10 mg tablet
- NDC 76282046318 rizatriptan 10 mg tablet
- NDC 00781542506 rizatriptan 5 mg tab rapdis
- NDC 00781542564 rizatriptan 5 mg tab rapdis
- NDC 00781542606 rizatriptan 10 mg tab rapdis
- NDC 00781542664 rizatriptan 10 mg tab rapdis
- NDC 00781548506 rizatriptan 5 mg tablet
- NDC 00781548564 rizatriptan 5 mg tablet
- NDC 00781548606 rizatriptan 10 mg tablet
- NDC 00781548664 rizatriptan 10 mg tablet
- NDC 78206014201 maxalt 10 mg tablet
- NDC 78206014299 maxalt 10 mg tablet
- NDC 78206014301 maxalt mlt 10 mg tab rapdis
- NDC 78206014399 maxalt mlt 10 mg tab rapdis
- NDC 82619011103 rizatriptan 5 mg tablet
- NDC 82619011104 rizatriptan 5 mg tablet
- NDC 82619011105 rizatriptan 5 mg tablet
- NDC 82619011203 rizatriptan 10 mg tablet
- NDC 82619011204 rizatriptan 10 mg tablet
- NDC 82619011205 rizatriptan 10 mg tablet
- NDC 00093747119 rizatriptan 5 mg tablet
- NDC 00093747143 rizatriptan 5 mg tablet
- NDC 00093747219 rizatriptan 10 mg tablet
- NDC 00093747243 rizatriptan 10 mg tablet

- Sumatriptan

- HCPCS J3030 injection, sumatriptan succinate, 6 mg
- NDC 00143963801 sumatriptan succinate 6 mg/0.5ml vial
- NDC 00143963805 sumatriptan succinate 6 mg/0.5ml vial
- NDC 15455001701 sumatriptan 100 % powder
- NDC 15455001702 sumatriptan 100 % powder
- NDC 15455001801 sumatriptan succinate 100 % powder
- NDC 16252059099 sumatriptan succinate 25mg tablet
- NDC 16252059199 sumatriptan succinate 50mg tablet
- NDC 16252059299 sumatriptan succinate 100mg tablet
- NDC 16590012709 imitrex 25mg tablet
- NDC 16590012809 imitrex 100mg tablet
- NDC 16714004001 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 16714004002 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 16714053110 sumatriptan succinate 25 mg tablet
- NDC 16714053111 sumatriptan succinate 25 mg tablet
- NDC 16714053210 sumatriptan succinate 50 mg tablet
- NDC 16714053211 sumatriptan succinate 50 mg tablet
- NDC 16714053310 sumatriptan succinate 100 mg tablet

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CT24-WI-GL15-RF02 5.0 Non-Interventional/Low-Interventional Study Type 1 Study Report Template

- NDC 16714053311 sumatriptan succinate 100 mg tablet
- NDC 16714079601 sumatriptan succinate 25 mg tablet
- NDC 16714079701 sumatriptan succinate 50 mg tablet
- NDC 16714079801 sumatriptan succinate 100 mg tablet
- NDC 16714089101 sumatriptan succ-naproxen sod 85mg-500mg tablet
- NDC 00173044901 imitrex 6mg/0.5ml kit-refill
- NDC 00173044902 imitrex 6mg/0.5ml vial
- NDC 00173044903 imitrex 6mg/0.5ml kit
- NDC 00173045003 imitrex 100mg tablet
- NDC 00173045900 imitrex 50mg tablet
- NDC 00173046002 imitrex 25mg tablet
- NDC 00173047800 imitrex 6mg/0.5ml kit-refill
- NDC 00173047900 imitrex 6mg/0.5ml kit
- NDC 00173052300 imitrex 20mg spray
- NDC 00173052400 imitrex 5mg spray
- NDC 00173073500 imitrex 25mg tablet
- NDC 00173073601 imitrex 50mg tablet
- NDC 00173073602 imitrex 50mg tablet
- NDC 00173073701 imitrex 100mg tablet
- NDC 00173073702 imitrex 100mg tablet
- NDC 00173073900 imitrex 4mg/0.5ml pen ij kit
- NDC 00173073902 imitrex 4mg/0.5ml cartridge
- NDC 00173075000 treximet 85mg-500mg tablet
- NDC 00173075049 treximet 85mg-500mg tablet
- NDC 21695087209 sumatriptan succinate 25 mg tablet
- NDC 21695087309 sumatriptan succinate 50mg tablet
- NDC 21695087409 sumatriptan succinate 100mg tablet
- NDC 21695095409 treximet 85mg-500mg tablet
- NDC 00245080938 zembrace symtouch 3 mg/0.5ml pen injctr
- NDC 00245080989 zembrace symtouch 3 mg/0.5ml pen injctr
- NDC 00245081261 tosymra 10 mg spray
- NDC 00245081289 tosymra 10 mg spray
- NDC 25021070360 sumatriptan succinate 6 mg/0.5ml vial
- NDC 25021070370 sumatriptan succinate 6 mg/0.5ml disp syrin
- NDC 27505000200 alsuma 6 mg/0.5ml pen ij kit
- NDC 35356025309 imitrex 50mg tablet
- NDC 35356025318 imitrex 50mg tablet
- NDC 35356025409 imitrex 100mg tablet
- NDC 35356039512 treximet 85mg-500mg tablet
- NDC 35356043809 sumatriptan succinate 100mg tablet
- NDC 35356043909 sumatriptan succinate 50mg tablet
- NDC 37803098206 sumatriptan succinate 100 % powder
- NDC 37803098210 sumatriptan succinate 100 % powder
- NDC 37803195203 sumatriptan succinate 100 % powder
- NDC 37803195204 sumatriptan succinate 100 % powder
- NDC 37803195205 sumatriptan succinate 100 % powder
- NDC 37803195207 sumatriptan succinate 100 % powder
- NDC 37803195208 sumatriptan succinate 100 % powder
- NDC 00378563059 sumatriptan succinate 25mg tablet

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CT24-WI-GL15-RF02 5.0 Non-Interventional/Low-Interventional Study Type 1 Study Report Template

- NDC 00378563159 sumatriptan succinate 50mg tablet
- NDC 00378563259 sumatriptan succinate 100mg tablet
- NDC 00378875559 sumatriptan succ-naproxen sod 85mg-500mg tablet
- NDC 38779270701 sumatriptan 100 % powder apr 30 2014
- NDC 38779270704 sumatriptan 100 % powder apr 30 2014
- NDC 38779270705 sumatriptan 100 % powder apr 30 2014
- NDC 38779270708 sumatriptan 100 % powder mar 11 2015
- NDC 38779270709 sumatriptan 100 % powder
- NDC 00395808919 sumatriptan succinate 100 % powder
- NDC 00395808962 sumatriptan succinate 100 % powder
- NDC 42023012105 sumatriptan succinate 6mg/0.5ml vial
- NDC 42043022000 sumatriptan succinate 25 mg tablet
- NDC 42043022009 sumatriptan succinate 25 mg tablet
- NDC 42043022100 sumatriptan succinate 50 mg tablet
- NDC 42043022109 sumatriptan succinate 50 mg tablet
- NDC 42043022200 sumatriptan succinate 100 mg tablet
- NDC 42043022209 sumatriptan succinate 100 mg tablet
- NDC 42254022009 sumatriptan succinate 25 mg tablet
- NDC 42254029701 sumavel dosepro 6 mg/0.5ml ndl fr inj
- NDC 42847031108 onzetra xsail 11 mg aer pow ba
- NDC 42847085009 treximet 85mg-500mg tablet
- NDC 43376010401 sumavel dosepro 4 mg/0.5ml ndl fr inj
- NDC 43376010406 sumavel dosepro 4 mg/0.5ml ndl fr inj
- NDC 43376010601 sumavel dosepro 6 mg/0.5ml ndl fr inj
- NDC 43376010606 sumavel dosepro 6mg/0.5ml ndl fr inj
- NDC 43598076811 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 43598076823 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 44183085009 sumatriptan succ-naproxen sod 85mg-500mg tablet
- NDC 45802059800 sumatriptan 20 mg spray
- NDC 45802059806 sumatriptan 20 mg spray
- NDC 45802061900 sumatriptan 5 mg spray
- NDC 45802061906 sumatriptan 5 mg spray
- NDC 45861005280 sumatriptan 100 % powder
- NDC 46144011410 sumatriptan succinate 100 % powder
- NDC 47335027640 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 47335027641 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 47335041022 sumatriptan succ-naproxen sod 85mg-500mg tablet
- NDC 49884048252 sumatriptan succinate 4mg/0.5ml cartridge
- NDC 49884048299 sumatriptan succinate 4mg/0.5ml pen ij kit
- NDC 49884048352 sumatriptan succinate 6mg/0.5ml cartridge
- NDC 49884048399 sumatriptan succinate 6mg/0.5ml pen ij kit
- NDC 49884051678 sumatriptan succinate 6 mg/0.5ml vial
- NDC 49999082206 imitrex 20mg spray
- NDC 50090112900 sumatriptan succinate 50 mg tablet
- NDC 50090113000 sumatriptan succinate 100 mg tablet
- NDC 50090214400 sumatriptan succinate 25 mg tablet
- NDC 50090291600 sumatriptan succinate 100 mg tablet
- NDC 50090593900 sumatriptan succinate 25 mg tablet
- NDC 50090743600 sumatriptan succinate 25 mg tablet

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- NDC 50436462201 sumatriptan succinate 25 mg tablet
- NDC 50436462301 sumatriptan succinate 50 mg tablet
- NDC 50436462401 sumatriptan succinate 100 mg tablet
- NDC 51407001109 sumatriptan succinate 25 mg tablet
- NDC 51407001209 sumatriptan succinate 50 mg tablet
- NDC 51407001309 sumatriptan succinate 100 mg tablet
- NDC 51552137604 sumatriptan succinate 100 % powder
- NDC 51759010101 zecuity 6.5 mg/4hr patch ioph
- NDC 51759010104 zecuity 6.5 mg/4hr patch ioph
- NDC 51927454200 sumatriptan succinate 100 % powder
- NDC 51927480200 sumatriptan succinate 100 % powder
- NDC 51927483900 sumatriptan 100 % powder
- NDC 52372067401 sumatriptan succinate 100 % powder
- NDC 52372067402 sumatriptan succinate 100 % powder
- NDC 52372067403 sumatriptan succinate 100 % powder
- NDC 00527181843 sumatriptan 5 mg spray
- NDC 00527185943 sumatriptan 20 mg spray
- NDC 52959042209 imitrex 25mg tablet
- NDC 52959047709 imitrex 50mg tablet
- NDC 52959051009 sumatriptan succinate 100 mg tablet
- NDC 52959090909 imitrex 100mg tablet
- NDC 54569370400 imitrex 6mg/0.5ml vial
- NDC 54569370500 imitrex 6mg/0.5ml kit
- NDC 54569370600 imitrex 6mg/0.5ml kit,refill
- NDC 54569419000 imitrex 25mg tablet
- NDC 54569419100 imitrex 50mg tablet
- NDC 54569419101 imitrex 50mg tablet
- NDC 54569450500 imitrex 6mg/0.5ml kit
- NDC 54569451100 imitrex 6mg/0.5ml kit-refill
- NDC 54569458800 imitrex 20mg spray
- NDC 54569542600 imitrex 100mg tablet
- NDC 54569542601 imitrex 100mg tablet
- NDC 54569646300 sumatriptan succinate 25 mg tablet
- NDC 54868265200 imitrex 6mg/0.5ml vial
- NDC 54868265201 imitrex 6mg/0.5ml vial
- NDC 54868318000 imitrex 6mg/0.5ml kit
- NDC 54868318100 imitrex 6mg/0.5ml kit
- NDC 54868377700 imitrex 25mg tablet
- NDC 54868385200 imitrex 50mg tablet
- NDC 54868395900 imitrex 6mg/0.5ml kit
- NDC 54868396000 imitrex 6mg/0.5ml kit-refill
- NDC 54868460600 imitrex 20mg spray
- NDC 54868476400 imitrex 5mg spray
- NDC 54868511800 imitrex 100mg tablet
- NDC 54868597800 sumatriptan succinate 100mg tablet
- NDC 54868602300 sumatriptan succinate 50mg tablet
- NDC 54868605200 sumatriptan 20 mg spray
- NDC 54868605200 sumatriptan 20 mg spray
- NDC 55045225009 imitrex 25mg tablet

- NDC 55045304009 imitrex 50mg tablet
- NDC 55045327101 imitrex 6mg/0.5ml cartridge
- NDC 55045350201 imitrex 20mg spray
- NDC 55045351201 imitrex 6mg/0.5ml vial
- NDC 55045373109 imitrex 100mg tablet
- NDC 55045373206 imitrex 5mg spray
- NDC 55111029109 sumatriptan succinate 25 mg tablet
- NDC 55111029136 sumatriptan succinate 25 mg tablet
- NDC 55111029190 sumatriptan succinate 25 mg tablet
- NDC 55111029198 sumatriptan succinate 25 mg tablet
- NDC 55111029209 sumatriptan succinate 50 mg tablet
- NDC 55111029236 sumatriptan succinate 50 mg tablet
- NDC 55111029290 sumatriptan succinate 50 mg tablet
- NDC 55111029298 sumatriptan succinate 50 mg tablet
- NDC 55111029309 sumatriptan succinate 100 mg tablet
- NDC 55111029336 sumatriptan succinate 100 mg tablet
- NDC 55111029390 sumatriptan succinate 100 mg tablet
- NDC 55111029398 sumatriptan succinate 100 mg tablet
- NDC 55111069305 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 55111069312 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 55111073609 sumatriptan succinate 50mg tablet
- NDC 55111073709 sumatriptan succinate 100mg tablet
- NDC 55111073809 sumatriptan succinate 25mg tablet
- NDC 55150017301 sumatriptan succinate 6 mg/0.5ml vial
- NDC 55150017305 sumatriptan succinate 6 mg/0.5ml vial
- NDC 55175405509 imitrex 25 mg tablet
- NDC 55390031510 sumatriptan succinate 6mg/0.5ml vial
- NDC 55390032502 sumatriptan succinate 6 mg/0.5ml disp syrin
- NDC 55700009209 sumatriptan succinate 25 mg tablet
- NDC 55700009230 sumatriptan succinate 25 mg tablet
- NDC 55700009330 sumatriptan succinate 50 mg tablet
- NDC 55700023509 sumatriptan succinate 25 mg tablet
- NDC 55812035201 sumatriptan succinate 100 % powder
- NDC 55812035202 sumatriptan succinate 100 % powder
- NDC 55812035203 sumatriptan succinate 100 % powder
- NDC 55887044109 imitrex 100 mg tablet
- NDC 55887051309 imitrex 25 mg tablet
- NDC 58016024609 imitrex 25 mg tablet
- NDC 58016123101 imitrex 20mg spray
- NDC 58016557409 imitrex 50 mg tablet
- NDC 58597808904 sumatriptan 100 % powder
- NDC 58597808907 sumatriptan 100 % powder
- NDC 58597808908 sumatriptan 100 % powder
- NDC 59088008300 migranow 50 mg kit gel-tb
- NDC 59762185003 sumatriptan succinate 25 mg tablet
- NDC 59762185009 sumatriptan succinate 25 mg tablet
- NDC 59762185103 sumatriptan succinate 50 mg tablet
- NDC 59762185109 sumatriptan succinate 50 mg tablet
- NDC 59762185203 sumatriptan succinate 100 mg tablet

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- NDC 59762185209 sumatriptan succinate 100 mg tablet
- NDC 60429099401 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 60429099402 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 60429099501 sumatriptan succinate 6 mg/0.5ml vial
- NDC 60429099505 sumatriptan succinate 6 mg/0.5ml vial
- NDC 60966059102 sumatriptan succinate 100 % powder
- NDC 60966059203 sumatriptan succinate 100 % powder
- NDC 60966059304 sumatriptan succinate 100 % powder
- NDC 61919030009 sumatriptan succinate 100 mg tablet
- NDC 61919095009 sumatriptan succinate 25 mg tablet
- NDC 62756052069 sumatriptan succinate 25 mg tablet
- NDC 62756052088 sumatriptan succinate 25 mg tablet
- NDC 62756052169 sumatriptan succinate 50 mg tablet
- NDC 62756052188 sumatriptan succinate 50 mg tablet
- NDC 62756052269 sumatriptan succinate 100mg tablet
- NDC 62756052288 sumatriptan succinate 100mg tablet
- NDC 62991309901 sumatriptan succinate 100 % powder
- NDC 62991309902 sumatriptan succinate 100 % powder
- NDC 62991310001 sumatriptan 100 % powder
- NDC 62991310002 sumatriptan 100 % powder
- NDC 62991310003 sumatriptan 100 % powder
- NDC 63187079709 sumatriptan succinate 50 mg tablet
- NDC 63187096909 sumatriptan succinate 25 mg tablet
- NDC 63304009711 sumatriptan succinate 25 mg tablet
- NDC 63304009711 sumatriptan succinate 25 mg tablet
- NDC 63304009719 sumatriptan succinate 25 mg tablet
- NDC 63304009811 sumatriptan succinate 50 mg tablet
- NDC 63304009819 sumatriptan succinate 50mg tablet
- NDC 63304009911 sumatriptan succinate 100 mg tablet
- NDC 63304009919 sumatriptan succinate 100 mg tablet
- NDC 63323027301 sumatriptan succinate 6 mg/0.5ml vial
- NDC 63323027385 sumatriptan succinate 6 mg/0.5ml syringe
- NDC 63323027485 sumatriptan succinate 4 mg/0.5ml syringe
- NDC 63481022901 sumavel dosepro 4 mg/0.5ml ndl fr inj
- NDC 63481022906 sumavel dosepro 4 mg/0.5ml ndl fr inj
- NDC 63481036706 sumavel dosepro 6 mg/0.5ml ndl fr inj
- NDC 63629870101 sumatriptan 5 mg spray
- NDC 63629870301 sumatriptan 20 mg spray
- NDC 64597031108 onzetra xsail 11 mg aer pow ba
- NDC 64679072801 sumatriptan succinate 6 mg/0.5ml vial
- NDC 64679072808 sumatriptan succinate 6 mg/0.5ml vial
- NDC 65145011801 sumatriptan succinate 6 mg/0.5ml vial
- NDC 65145011805 sumatriptan succinate 6 mg/0.5ml vial
- NDC 65224085009 treximet 85mg-500mg tablet
- NDC 65224086009 treximet 10 mg-60mg tablet
- NDC 65862014636 sumatriptan succinate 25 mg tablet
- NDC 65862014736 sumatriptan succinate 50 mg tablet
- NDC 65862014836 sumatriptan succinate 100 mg tablet
- NDC 65862092836 sumatriptan succ-naproxen sod 85mg-500mg tablet

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- NDC 66860002206 sumatriptan succinate 6 mg/0.5ml vial
- NDC 66993008169 sumatriptan 5 mg spray
- NDC 66993008269 sumatriptan 20 mg spray
- NDC 66993008379 sumatriptan succinate 4 mg/0.5ml cartridge
- NDC 66993008398 sumatriptan succinate 4 mg/0.5ml pen injctr
- NDC 66993008479 sumatriptan succinate 6 mg/0.5ml cartridge
- NDC 66993008498 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 67457087900 sumatriptan succinate 6 mg/0.5ml syringe
- NDC 67457087905 sumatriptan succinate 6 mg/0.5ml syringe
- NDC 67457088000 sumatriptan succinate 6 mg/0.5ml vial
- NDC 67457088005 sumatriptan succinate 6 mg/0.5ml vial
- NDC 67857080937 zembrace symtouch 3 mg/0.5ml pen injctr
- NDC 67857080938 zembrace symtouch 3 mg/0.5ml pen injctr
- NDC 67857081261 tosymra 10 mg spray
- NDC 67857081262 tosymra 10 mg spray
- NDC 68084033911 sumatriptan succinate 25 mg tablet
- NDC 68084033996 sumatriptan succinate 25 mg tablet
- NDC 68084033997 sumatriptan succinate 25 mg tablet
- NDC 68084034011 sumatriptan succinate 50mg tablet
- NDC 68084034096 sumatriptan succinate 50 mg tablet
- NDC 68084034097 sumatriptan succinate 50mg tablet
- NDC 68084034111 sumatriptan succinate 100mg tablet
- NDC 68084034196 sumatriptan succinate 100 mg tablet
- NDC 68084034197 sumatriptan succinate 100mg tablet
- NDC 68115069609 imitrex 50mg tablet
- NDC 68115077002 imitrex 6mg/0.5ml kit
- NDC 68115090709 imitrex 100mg tablet
- NDC 68258300801 sumatriptan succinate 50mg tablet
- NDC 68258300901 sumatriptan succinate 100mg tablet
- NDC 69097064448 sumatriptan 20 mg spray
- NDC 69452034460 sumatriptan succinate 25 mg tablet
- NDC 69452034472 sumatriptan succinate 25 mg tablet
- NDC 69452034560 sumatriptan succinate 50 mg tablet
- NDC 69452034572 sumatriptan succinate 50 mg tablet
- NDC 69452034660 sumatriptan succinate 100 mg tablet
- NDC 69452034672 sumatriptan succinate 100 mg tablet
- NDC 70069080401 sumatriptan succinate 6 mg/0.5ml vial
- NDC 70069080405 sumatriptan succinate 6 mg/0.5ml vial
- NDC 00703735101 sumatriptan succinate 6mg/0.5ml vial
- NDC 00703735102 sumatriptan succinate 6 mg/0.5ml vial
- NDC 70594006801 sumatriptan succinate 6 mg/0.5ml vial
- NDC 70594006802 sumatriptan succinate 6 mg/0.5ml vial
- NDC 71205025109 sumatriptan succinate 50 mg tablet
- NDC 71800090101 sumatriptan succ-naproxen sod 85mg-500mg tablet
- NDC 71921017061 sumatriptan 20 mg spray
- NDC 72189040409 sumatriptan succinate 100 mg tablet
- NDC 72189043209 sumatriptan succinate 25 mg tablet
- NDC 72189043309 sumatriptan succinate 50 mg tablet
- NDC 72189059609 sumatriptan succinate 25 mg tablet

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CT24-WI-GL15-RF02 5.0 Non-Interventional/Low-Interventional Study Type 1 Study Report Template

- NDC 72603014101 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 72603014102 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 75839037450 sumatriptan succinate 100 % powder
- NDC 76420049809 sumatriptan succinate 50 mg tablet
- NDC 76420049909 sumatriptan succinate 25 mg tablet
- NDC 76420050009 sumatriptan succinate 100 mg tablet
- NDC 00781316907 sumatriptan succinate 4 mg/0.5ml pen injctr
- NDC 00781317007 sumatriptan succinate 4 mg/0.5ml cartridge
- NDC 00781317207 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 00781317307 sumatriptan succinate 6mg/0.5ml cartridge
- NDC 00781317414 sumatriptan succinate 6mg/0.5ml vial
- NDC 00781317471 sumatriptan succinate 6mg/0.5ml vial
- NDC 00781323147 sumatriptan succinate 4mg/0.5ml vial
- NDC 00781652306 sumatriptan 20mg spray
- NDC 00781652386 sumatriptan 20mg spray
- NDC 00781652406 sumatriptan 5mg spray
- NDC 00781652486 sumatriptan 5mg spray
- NDC 80425047501 sumatriptan succinate 50 mg tablet
- NDC 00093022219 sumatriptan succinate 25 mg tablet
- NDC 00093022290 sumatriptan succinate 25mg tablet
- NDC 00093022319 sumatriptan succinate 50 mg tablet
- NDC 00093022390 sumatriptan succinate 50mg tablet
- NDC 00093022419 sumatriptan succinate 100 mg tablet
- NDC 00093022490 sumatriptan succinate 100mg tablet
- NDC 00093201312 sumatriptan succinate 4 mg/0.5ml pen injctr
- NDC 00093201334 sumatriptan succinate 4 mg/0.5ml pen injctr
- NDC 00093201412 sumatriptan succinate 6 mg/0.5ml pen injctr
- NDC 00093201434 sumatriptan succinate 6 mg/0.5ml pen injctr

#### Zolmitriptan

- NDC 00115067151 zolmitriptan 2.5 mg tablet
- NDC 00115067250 zolmitriptan 5 mg tablet
- NDC 00115069151 zolmitriptan odt 2.5 mg tab rapdis
- NDC 00115069250 zolmitriptan odt 5 mg tab rapdis
- NDC 16571080316 zolmitriptan 2.5 mg tablet
- NDC 16571080413 zolmitriptan 5 mg tablet
- NDC 16590076003 zomig 5 mg tablet
- NDC 21695095506 zomig 5 mg spray
- NDC 27241002168 zolmitriptan 2.5 mg tablet
- NDC 27241002238 zolmitriptan 5 mg tablet
- NDC 00310020860 zomig 5mg spray
- NDC 00310020920 zomig zmt 2.5mg tab rapdis
- NDC 00310021020 zomig 2.5mg tablet
- NDC 00310021125 zomig 5mg tablet
- NDC 00310021321 zomig zmt 5mg tab rapdis
- NDC 31722045806 zolmitriptan 2.5 mg tablet
- NDC 31722045903 zolmitriptan 5 mg tablet
- NDC 33342011274 zolmitriptan 2.5 mg tablet
- NDC 33342011352 zolmitriptan 5 mg tablet

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- NDC 33342013974 zolmitriptan odt 2.5 mg tab rapdis
- NDC 33342014052 zolmitriptan odt 5 mg tab rapdis
- NDC 35356041203 zomig 5mg tablet
- NDC 00037720860 zomig 5mg spray
- NDC 00037720920 zomig zmt 2.5mg tab rapdis
- NDC 00037721020 zomig 2.5mg tablet
- NDC 00037721125 zomig 5mg tablet
- NDC 00037721321 zomig zmt 5mg tab rapdis
- NDC 00378426056 zolmitriptan 2.5 mg tablet
- NDC 00378426153 zolmitriptan 5 mg tablet
- NDC 45802071100 zolmitriptan 5 mg spray
- NDC 45802071191 zolmitriptan 5 mg spray
- NDC 47335097860 zolmitriptan 2.5 mg tablet
- NDC 47335097863 zolmitriptan 2.5 mg tablet
- NDC 47335097960 zolmitriptan 5 mg tablet
- NDC 47335097967 zolmitriptan 5 mg tablet
- NDC 50742062506 zolmitriptan 2.5 mg tablet
- NDC 50742062603 zolmitriptan 5 mg tablet
- NDC 54569461200 zomig 2.5mg tablet
- NDC 54868008500 zomig zmt 5mg tab rapdis
- NDC 54868008501 zomig zmt 5mg tab rapdis
- NDC 54868408600 zomig 5mg tablet
- NDC 54868421500 zomig 2.5mg tablet
- NDC 54868536100 zomig 5mg spray
- NDC 54868559300 zomig zmt 2.5mg tab rapdis
- NDC 59746043204 zolmitriptan 2.5 mg tablet
- NDC 59746043216 zolmitriptan 2.5 mg tablet
- NDC 59746043304 zolmitriptan 5 mg tablet
- NDC 59746043313 zolmitriptan 5 mg tablet
- NDC 59746046116 zolmitriptan odt 2.5 mg tab rapdis
- NDC 59746046213 zolmitriptan odt 5 mg tab rapdis
- NDC 60505369300 zolmitriptan 2.5 mg tablet
- NDC 60505369400 zolmitriptan 5 mg tablet
- NDC 60505371800 zolmitriptan odt 2.5 mg tab rapdis
- NDC 60505371900 zolmitriptan odt 5 mg tab rapdis
- NDC 60846013030 zomig 2.5 mg tablet
- NDC 60846013360 zomig 5 mg tablet
- NDC 60846238303 zomig 2.5 mg tablet
- NDC 60846238404 zomig 5 mg tablet
- NDC 62332018106 zolmitriptan odt 2.5 mg tab rapdis
- NDC 62332018203 zolmitriptan odt 5 mg tab rapdis
- NDC 62332046206 zolmitriptan 2.5 mg tablet
- NDC 62332046303 zolmitriptan 5 mg tablet
- NDC 63629957501 zolmitriptan 5 mg spray
- NDC 64896008312 zomig 2.5 mg spray
- NDC 64896008412 zomig 5 mg spray
- NDC 64896067151 zomig 2.5 mg tablet
- NDC 64896067250 zomig 5 mg tablet
- NDC 64896068151 zomig 5 mg spray

- NDC 64896068251 zomig 2.5 mg spray
- NDC 64896069151 zomig zmt 2.5 mg tab rapdis
- NDC 64896069250 zomig zmt 5 mg tab rapdis
- NDC 64980020316 zolmitriptan 2.5 mg tablet
- NDC 64980020413 zolmitriptan 5 mg tablet
- NDC 64980025616 zolmitriptan odt 2.5 mg tab rapdis
- NDC 64980025713 zolmitriptan odt 5 mg tab rapdis
- NDC 65862091406 zolmitriptan 2.5 mg tablet
- NDC 65862091469 zolmitriptan 2.5 mg tablet
- NDC 65862091503 zolmitriptan 5 mg tablet
- NDC 65862091564 zolmitriptan 5 mg tablet
- NDC 68001024901 zolmitriptan 2.5 mg tablet
- NDC 68001024919 zolmitriptan 2.5 mg tablet
- NDC 68001025001 zolmitriptan 5 mg tablet
- NDC 68001025018 zolmitriptan 5 mg tablet
- NDC 68115072506 zomig 5mg spray
- NDC 68382071569 zolmitriptan odt 2.5 mg tab rapdis
- NDC 68382071586 zolmitriptan odt 2.5 mg tab rapdis
- NDC 68382071782 zolmitriptan odt 5 mg tab rapdis
- NDC 68382071787 zolmitriptan odt 5 mg tab rapdis
- NDC 68462049776 zolmitriptan 2.5 mg tablet
- NDC 68462049833 zolmitriptan 5 mg tablet
- NDC 68462049940 zolmitriptan odt 2.5 mg tab rapdis
- NDC 68462049976 zolmitriptan odt 2.5 mg tab rapdis
- NDC 68462050033 zolmitriptan odt 5 mg tab rapdis
- NDC 68462050040 zolmitriptan odt 5 mg tab rapdis
- NDC 69097086317 zolmitriptan 2.5 mg tablet
- NDC 69097086484 zolmitriptan 5 mg tablet
- NDC 69238200606 zolmitriptan 2.5 mg spray
- NDC 69238200706 zolmitriptan 5 mg spray
- NDC 69238235106 zolmitriptan 2.5 mg spray
- NDC 69238235206 zolmitriptan 5 mg spray
- NDC 71626010106 zolmitriptan 2.5 mg tablet
- NDC 71626010203 zolmitriptan 5 mg tablet
- NDC 72189043406 zolmitriptan 2.5 mg tablet
- NDC 72189043503 zolmitriptan 5 mg tablet
- NDC 72606056701 zolmitriptan 2.5 mg tablet
- NDC 72606056801 zolmitriptan 5 mg tablet
- NDC 75839037601 zolmitriptan 100 % powder

Ditans: lasmiditan

- NDC 00002431208 Reyvow 50 mg tablet
- NDC 00002449101 Reyvow 100 mg tablet
- NDC 00002449108 Reyvow 100 mg tablet

## Document Approval Record

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