# Post Marketing Active Surveillance to Evaluate the Safety and Efficacy of Aprepitant (EMEND®) for the Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV) Associated with High Emetogenic Cancer Chemotherapy in China (MK-0869-804)

**First published:** 11/07/2019

**Last updated:** 27/02/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS29952

**Study ID**

29953

**DARWIN EU® study**

No

**Study countries**

China

**Study description**

This was a multi-center, prospective, non-interventional surveillance study to assess the safety and efficacy of aprepitant in the prevention of chemotherapy-induced nausea and vomiting (CINV) in Chinese participants with solid malignancies who were treated with a highly emetogenic chemotherapy (HEC) regimen. Participants received 125 mg of oral aprepitant one hour prior to HEC chemotherapy on Day 1 and 80 mg of oral aprepitant once daily on the mornings of Days 2 and 3. Participants who took at least one dose of aprepitant were surveyed using diaries that included the following: the Multinational Association of Supportive Care in Cancer (MASCC) Antiemesis Tool (MAT), Functional Living Index-Emesis (FLIE) questionnaire, and a medication questionnaire. In addition, participants were contacted by investigators to assess adverse event (AE) up to 14 days after the last dose of aprepitant.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

United States

**First published:** 01/02/2024

**Last updated:** 08/07/2025

Institution | Pharmaceutical company

The First Affiliated Hospital of Medical School of Zhejiang University Hangzhou, Zhejiang Province, People's Republic of China

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 30/01/2014

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**Study start date**

Actual: 15/07/2014

**Data analysis start date**
Actual: 25/04/2016

**Date of final study report**
Actual: 20/10/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme Corp.

## Regulatory

**Was the study required by a regulatory body?**

Yes

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

This was a non-interventional surveillance study to assess the safety and efficacy of aprepitant in the prevention of chemotherapy-induced nausea and vomiting (CINV) in Chinese participants with solid malignancies who were treated with a highly emetogenic chemotherapy (HEC) regimen.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Single-arm, prospective, post-marketing surveillance study

## Study drug and medical condition

**Medicinal product name**

EMEND

**Anatomical Therapeutic Chemical (ATC) code**

(A04AD12) aprepitant

aprepitant

**Medical condition to be studied**

Nausea

Vomiting

# Population studied

**Short description of the study population**

Chinese patients, 18 years of age or above, both males and females, with a solid malignancy, who are treated with HEC regimens. To participate in this surveillance, patients are those who received at least one dose of Aprepitant, prior to HEC regimen.

Inclusion Criteria

All inclusion and exclusion criteria will be reviewed by the investigator or qualified designee to ensure the patient is qualified for the survey.

1. Adult male or female, 18 years Of age Or Older.
2. Patient must be willing to give written infonned consent.
3. Patient is scheduled to receive his/her highly emetogenie chemotherapy.
4. Patient who is treated with Aprepitant for the first time.
5. Patient is able to read, understand and complete the patient diaries.

Exclusion Criteria

1. Patient having any medical condition or concurrent use Of medications, which may be contraindication to the approved local prescribing information as per the investigator's opinion. Contraindication to Aprepitant.
The patient who has one or more of the following conditions:
i) Aprepitant is a moderate cytoehrome P450 isoenzyme 3A4 (CYP3A4) inhibitor. Aprepitant should not be used concurrently with pimozide, terfenadine, astemizole, or eisapride. Inhibition Of CYP3A4 by Aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions.
ii) Aprepitant is contraindicated in patients who are hypersensitive to any component of the product.
2. Patient has received a non-approved (investigational) drug within the last 4 weeks.
3. Any condition which, in the opinion of the investigator may confound the results of the survey or pose unwarranted risk in administering study drug to the patient.

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**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Special population of interest**

Other

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**Special population of interest, other**

Solid malignancy patients

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**Estimated number of subjects**

1000

# Study design details

**Outcomes**

The primary outcome was related to safety and included the proportion of one or more of the following: adverse event(s), drug-related adverse event(s), serious adverse event(s), and discontinuations due to an adverse event(s). The secondary outcome was related to efficacy and included complete response at 0 to 120, 0 to 24, and 25 to 120 hours, no vomiting at 0 to 24, 25 to 120, and 0 to 120 hours, no significant nausea at 0 to 120 hours, no nausea at 0 to 120 hours, and no impact on daily life at 0 to 120 hours.

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**Data analysis plan**

The primary outcomes were summarized by number of events, observed incidence, and corresponding 95% CI (Clopper-Pearson) by descriptive statistics. The primary outcome was further analyzed by: age (<55, >=55 years), gender, and clinical characteristics derived by medical history including chemotherapy regimen(s), cancer diagnosis, clinically significant prior/concomitant medications (including Traditional Chinese Medicines), and the timing of aprepitant administration.The secondary outcomes were summarized by count, point estimate and corresponding 95% confidence interval (Clopper-Pearson), and analyzed by: age (<55, >=55 years), gender, and clinical characteristics derived by medical history including chemotherapy regimen(s), cancer diagnosis, clinically significant prior/concomitant medications (including Traditional Chinese Medicines), and the timing of aprepitant administration.

# Data management

# ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

# Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection, Multinational Association of Supportive Care in Cancer (MASCC) Antiemesis Tool (MAT), Functional Living Index-Emesis (FLIE) questionnaire, and a medication questionnaire

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No