Annual investigate of EMEND prescription

First published: 02/12/2013

Last updated: 30/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/19569

EU PAS number

EUPAS5333

Study ID

19569

DARWIN EU® study

No

Study countries

☐ France

Study description

EMEND® (aprepitant) is an anti-emetic drug indicated for the prevention of nausea and vomiting associated with acute and delayed highly emetogenic cancer chemotherapy including cisplatin, and with moderately emetogenic chemotherapy.Annual monitoring of the conditions of use of this drug has been requested to MSD France laboratory by the Transparency Committee and the Economic Committee for Health Products.Using Onco-Analyser/IMS Health database, the objective of the study is to check EMEND® compliance in real life: profile of patients, type of cancer, chemotherapy and/or other previous treatments, daily dose, duration of treatment and associated treatments, and to make an annual follow-up of the respect of the conditions of use of EMEND® in comparison with the Therapeutic Information Sheet, over 8 years.

Study status

Finalised

Research institutions and networks

Institutions

Université Claude Bernard Lyon 1

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Eric VAN GANSE

Study contact

eric.van-ganse@univ-lyon1.fr

Primary lead investigator

Eric VAN GANSE

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/01/2005

Study start date

Actual: 01/09/2005

Date of final study report

Planned: 28/02/2014

Actual: 15/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD FRANCE

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Prescription compliance

Data collection methods:

Secondary use of data

Main study objective:

The main objective is to check EMEND® prescription compliance in real life

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Name of medicine

EMEND

Population studied

Short description of the study population

Cancer patients identified from Onco-Analyser/IMS Health database.

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)

Special population of interest

Other

Special population of interest, other

Cancer patients

Estimated number of subjects

10000

Study design details

Outcomes

profile of patients, type of cancer, chemotherapy and/or other previous treatments, daily dose, duration of treatment and associated treatments, and to make an annual follow-up of the respect of the conditions of use of EMEND® in comparison with the Therapeutic Information Sheet, over 8 years.

Data analysis plan

This is an observational descriptive cross-sectional study conducted among a panel representative of the doctors in charge of patients with cancer.The results are expressed in patients without extrapolation case:• Description of the population:o Distribution by sexo Distribution by age: 50 years and under, 51-60 years, 61-70 years, 71-80 years, over 80 yearso Distribution by type of cancer• Analysis of Emend prescription conditions:o Distribution by type of treatment (chemotherapy, radiotherapy, surgery)o Distribution according to emetogenic chemotherapy (with cisplatin, high, medium or low emetogenic)• Analysis of EMEND prescription:o Distribution by duration of treatment: 1 day, 2 days, 3 days,> 3 dayso Daily Doseo associated antiemetic treatments

Data management

Data sources

Data source(s), other

IMS ONCOANALYSER France

Data sources (types)

Other

Data sources (types), other

Prescription event monitoring

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

Unknown