Rapid Data Analysis (RDA) – Amfepramone drug utilisation

First published: 24/03/2021

Last updated: 24/03/2021

Study Finalised

Administrative details

EU PAS number

EUPAS40283

Study ID

40284

DARWIN EU® study

No

Study countries

Germany

Study description

Amfepramone is an amphethamine-derivative, a sympathomimetic agent with indirect action, belonging to the group of anorexigens. Substances in this group inhibit the hunger centre. However, it has not yet been established whether the

action of these drugs in appetite reduction is of primary importance in the treatment of obesity. There are also other effects on the central nervous system and metabolism, connected with the anorexigenic action. The evolution of drug utilisation over time and the trends regarding length of use are currently unknown. This study is therefore aimed at evaluating drug utilisation trends over the last years in Germany and to estimate the usual length of usage and compliance with past regulatory recommendation for short treatment periods of up to 3 months. This RDA was agreed with DK (Rapporteur for the Article 31 referral procedure triggered in 2021) in complement to the study currently performed by DKMA in Danish registries.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Karin Hedenmalm ICU@ema.europa.eu

Study contact

ICU@ema.europa.eu

Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/02/2021

Actual: 02/02/2021

Study start date

Planned: 02/02/2021

Actual: 02/02/2021

Date of final study report

Planned: 23/03/2021

Actual: 23/03/2021

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

No

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To evaluate drug utilisation trends and duration of treatment of amfepramone between 1 January 1998 to 30 June 2020, To evaluate the total long-term usage over the entire period of the cohort, To provide incidence rates for selected CV

events in patients with no history of such events: Valvular disorders, Pulmonary heart disease, Cardiomyopathy, Heart failure, Essential (primary) hypertension.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study of patients in general practices (GP)

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

AMFEPRAMONE

Population studied

Short description of the study population

Patients in general practices (GP) receiving at least one prescription with amfepramone over the studied period.
Between January 1998 and June 2020 a total of 7204 patients in GP practices had 24,275 prescriptions (prescription dates) for amfepramone. Of these patients, 4825 had an incident prescription.

Age groups

- Adolescents (12 to < 18 years)

- 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)

Estimated number of subjects

4000

Study design details

Data analysis plan

Descriptive analyses were performed to derive further insight regarding drug utilization trends and prescription duration of amfepramone use + Calculation of incidence rates and incidence proportions, see section 6.8.1 of the report

Documents

Study results

Amfepramone RDA report on results.pdf (549.43 KB)

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 source(s), other

IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

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