Drug Utilization Study to Characterize the Prescribing Practice of Flupirtine-containing Medicinal Products during Typical Clinical Use and to Assess the Main Reason for Prescription (Flupirtine-3304)

First published: 22/01/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS12177

Study ID

23066

DARWIN EU® study

No

Study countries

Germany

Study description

This study will employ a retrospective cohort analysis of the IMS® Disease Analyzer database in four annual time intervals from calendar years 2012 until 2015, for Germany and all flupirtine-containing products to analyse the prescribing practice of flupirtine-containing medicinal products during typical clinical use.

Study status

Finalised

Research institutions and networks

Institutions

MEDA Pharma

Contact details

Study institution contact

Dennis Castor Dennis.Castor@mylan.com

Study contact

Dennis.Castor@mylan.com

Primary lead investigator

N/A N/A

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/10/2014

Actual: 17/10/2014

Study start date
Planned: 01/01/2012

Actual: 01/01/2012

Date of interim report, if expected
Planned: 30/06/2015

Actual: 23/06/2015

Date of final study report
Planned: 30/06/2016

Actual: 17/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MEDA Pharma

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The overall research goal of this DUS is to describe and analyse the prescribing practice of all flupirtine-containing medicinal products in Germany during typical use in representative groups of prescribers and to assess the main reason for prescription.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective cohort analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02BG07) flupirtine

flupirtine

Medical condition to be studied

Pain

Population studied

Short description of the study population

All flupirtine-containing medicinal products prescribers in Germany.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- 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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

84000

Study design details

Data analysis plan

Statistical analyses will be exploratory using descriptive and inferential statistics. Categorical data will be summarized in contingency tables presenting frequencies and percentages (rates), with 95% confidence intervals of rates, where appropriate.

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

Unknown