Drug utilisation study (DUS) on flupirtine-containing products Retrospective drug utilisation study using patient-level databases to characterise prescribing practices of flupirtine-containing drugs during routine clinical use and assess the main reasons for prescription by representative groups of prescribers

First published: 26/10/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11391

Study ID

23426

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Cohort study with pre-post design using a longitudinal patient level Electronic Medical Records (EMR) database and a longitudinal patient level prescription database for Germany. The DUS will be carried out in Germany because more than 90% of total prescriptions for flupirtine-containing medicinal products of MAHs in European Union Member States were issued in Germany.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

☐ France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Toussi Massoud

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2015

Actual: 30/09/2015

Study start date

Planned: 01/10/2016

Actual: 01/10/2016

Date of final study report

Planned: 31/12/2016

Actual: 11/11/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TEVA

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives of the study are to describe before and after the implementation of risk minimisation measures for flupirtine-containing medicinal products.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

FLUPIRTINE

FLUPIRTINE MALEATE

FLUPIRTINE GLUCONATE

Medical condition to be studied

Pain

Population studied

Short description of the study population

All patients who have received at least one prescription for flupirtine –containing products in the reference period or in the assessment periods I or II and fulfilled the inclusion criteria from IMS® Disease Analyzer and from IMS® LRx were included.

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

13700

Study design details

Data analysis plan

Data from both databases will not be combined. The data will be analysed separately by data source (IMS® Disease Analyzer and IMS® LRx) and by physician panel.The statistical unit will be the patient (for information such as demographical and clinical characteristics, medical history, contraindications) and the flupirtine prescription (for information such as indication, number of packages, pack size, strength, number of prescriptions, recommended treatment duration, concomitant drug prescriptions, liver function tests).The analyses will be performed separately for the reference period, assessment period I and assessment period II. The analyses will be provided for the total population and will be stratified by incident and prevalent users.The statistical analysis will be done descriptively. Missing values will be reported as missing and no imputation will be conducted. Descriptive tables will be compiled for all variables.

Documents

Study results

Abstract- Flupirtine DUS..pdf (61.95 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)

IQVIA Disease Analyzer Germany

Data source(s), other

IMS Lifelink Longitudinal Prescriptions (LRx) Germany

Data sources (types)

Drug dispensing/prescription data

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