Drug utilisation study (DUS) on flupirtine-containing medicinal products

First published: 01/02/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12241

Study ID

23309

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Retrospective drug utilisation study using patient-level databases to characterise prescribing practice of flupirtine-containing medicinal products during routine clinical use and assess the main reasons for prescription by

representative groups of prescribers

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

Karel Kostev

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/09/2015

Actual: 02/11/2015

Study start date
Planned: 02/11/2015

Actual: 02/11/2015

Data analysis start date
Planned: 09/11/2015

Actual: 09/11/2015

Date of final study report
Planned: 29/02/2016

Actual: 25/02/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Lupin

Study protocol

2015-09-25_DUS Flupirtine study protocol _Version3_1.pdf (570.67 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Assessment of prescribing and Treatment Patterns of flupirtine-containing medical products during Routine use in the out Patient Settings before and after the Revision of SmPC.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02BG07) flupirtine

flupirtine

Population studied

Short description of the study population

All outpatients in Germany with a record of either single or recurrent use of Flupirtine prescription during the defined 12-month periods (patient selection window) identified from IMS® Disease Analyzer.

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

10000

Study design details

Outcomes

- Main reason for prescription- Amount of patients contraindicated for the use of NSAIDs/weak Opioids- Treatment Duration- Share of single/repeated prescriptions- Lenght of Treatment episodes- Amount of Liver Function Test-

Concomitant Treatment and diseases

Data analysis plan

Descriptive Analysis showing Treatment Patterns and main reason for prescription.No statistical testing.Data source is represetative IMS Disease Analyzer database Panel General practicioner and orhtopaedists.

Documents

Study results

2a_DUS_Flupirtine_Report_IMS_final_v2.0_clean.pdf (1.48 MB)

Study, other information

DUS_Signature page.pdf (241.1 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

Unknown