Drug utilisation study (DUS) on flupirtinecontaining medicinal products

First published: 01/02/2016 Last updated: 31/03/2024





Administrative details

PURI

https://redirect.ema.europa.eu/resource/23309

EU PAS number

EUPAS12241

Study ID

23309

DARWIN EU® study

No

Study countries

Germany

Study description

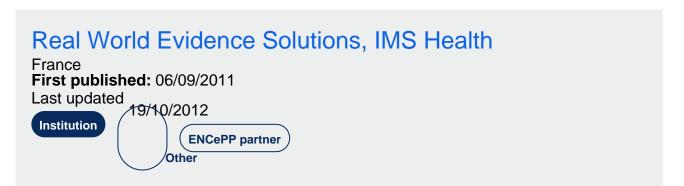
Retrospective drug utilisation study using patient-level databases to characterise prescribing practice of flupirtine-containing medicinal products during routine clinical use and assess the main reasons for prescription by representative groups of prescribers

Study status

Finalised

Research institution and networks

Institutions



Contact details

Study institution contact

Silvia Dombrowski

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

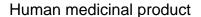
Is the study required by a Risk Management Plan (RMP)?

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

Methodological aspects

Study type list

Study topic:



Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary data collection

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

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 representative 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

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