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

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

Study | Finalised

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

Real World Evidence Solutions, IMS Health

France
First published: 06/09/2011
Last updated
19/10/2012

Institution
ENCePP partner
Other

Contact details

Study institution contact
Silvia Dombrowski
Study contact

sdombrowski@de.imshealth.com
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 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 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

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