# 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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**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

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**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

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**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

# Data sources

**Data source(s)**

IQVIA Disease Analyzer Germany

**Data source(s), other**

IMS Lifelink Longitudinal Prescriptions (LRx) Germany

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**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

Unknown