# Drug utilisation study (DUS) on flupirtinecontaining medicinal products

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## Administrative details

### **Study description**

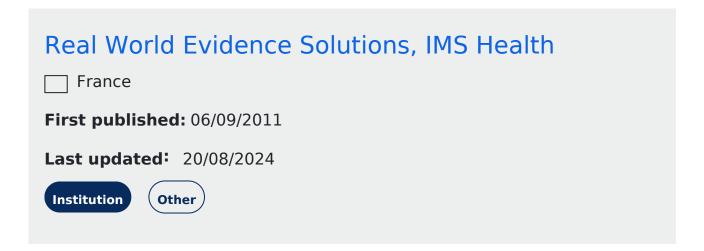
Retrospective drug utilisation study using patient-level databases to characterise prescribing practice of flupirtine-containing medicinal products during routine clinical use and assess the main reasons for prescription by

#### **Study status**

**Finalised** 

### Research institutions and networks

### Institutions



## Contact details

### **Study institution contact**

Silvia Dombrowski sdombrowski@de.imshealth.com



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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-

#### 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

### **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