

Post-Authorisation Safety Study (PASS) on Flupirtine-containing Medicinal Products - A retrospective, multicentre, non-interventional study to evaluate the effectiveness of the risk minimisation activities for flupirtine-containing medicinal products

First published: 12/11/2015

Last updated: 31/03/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS11571

Study ID

33294

DARWIN EU® study

No

Study countries

 Germany

Study description

This study protocol was developed in the context of the European Medicines Agency (EMA) referral (article 107i of Directive 2001/83/EC EMEA/H/A-107i/1363) on the benefit and risks of the use of flupirtine. The study is required as part of the risk management plan (RMP) in order to assess the effectiveness of the risk minimisation measures as laid down in the revised Summary of Product Characteristics (SmPC) into therapy practice. The primary objective of this study is to evaluate the overall percentage of patients treated according to the revised SmPC.

Study status

Finalised

Research institutions and networks

Institutions

SocraTec R&D GmbH

Multiple centres: 165 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Frank Donath

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/10/2015

Study start date

Actual: 21/10/2015

Date of final study report

Planned: 28/11/2016

Actual: 23/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TEVA GmbH

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

Data collection methods:

Secondary use of data

Main study objective:

The study is required as part of the RMP in order to evaluate the effectiveness of the risk minimisation measures (RMM) as laid down in the revised Summary

of Product Characteristics (SmPC) in the therapy practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This Post-Authorisation Safety Study (PASS) is a retrospective, multicentre, non-interventional study in patients treated with flupirtine-containing medicinal products.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02BG07) flupirtine

flupirtine

Medical condition to be studied

Pain

Population studied

Short description of the study population

Patients treated with flupirtine-containing medicinal products.

Age groups

- 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

2000

Study design details

Outcomes

Overall percentage of patients treated with flupirtine before and after implementation of the RMM for flupirtine-containing medicinal products determined as composite endpoint, Percentage of patients with abnormal liver function tests, Percentage of patients in whom flupirtine treatment was discontinued due to abnormal liver function tests, Percentage of patients experiencing hepatic adverse events classified according to SMQ hepatic disorders, Frequency, nature and intensity of Adverse Events (AEs)

Data analysis plan

Data analysis in the study was descriptive. Descriptive statistics were presented including number of patients, mean, standard deviation, median, minimum, and maximum for continuous variables, and number and percentage of patients per category for categorical variables. Whenever meaningful, point estimates and 95 % confidence intervals were calculated. Furthermore, parameters from pre- and post-intervention periods were compared and a sensitivity analysis in regard to duration of treatment and its effect on liver parameters was realised.

Documents

Study results

[Flupirtine PASS Abstract.pdf](#) (145.48 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 sources (types)

[Other](#)

Data sources (types), other

Data of this PASS derived from the patients' medical records and were collected by using a case report form (CRF) specified to the study purpose.

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