Retrospective Chart Review to Evaluate the Effectiveness of the Risk Minimization Measures for the Use of Flupirtine 100 mg Immediate-Release Capsules in daily Practice (Flupirtine-3300)

First published: 30/09/2015

Last updated: 01/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS11134

Study ID

28844

DARWIN EU® study

No

Study countries

Germany

Portugal

Study description

This is a company-sponsored international, multicenter, non-interventional post-authorization safety study (PASS) in the form of a retrospective chart review (RCR) in a cohort of outpatients treated with flupirtine IR in daily practice in Germany and Portugal. The overall research goal is to assess the effectiveness of the risk minimization measures for flupirtine 100 mg immediate-release capsules (flupirtine IR) by evaluating to which extent these measures are implemented in daily practice.

Study status

Finalised

Research institutions and networks

Institutions

MEDA Pharma

Multiple centres: 120 centres are involved in the study

Contact details

Study institution contact

Dennis Castor Dennis.Castor@mylan.com

Study contact

Dennis.Castor@mylan.com

Primary lead investigator

N/A N/A

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/10/2015

Actual: 15/10/2015

Study start date

Planned: 01/11/2015

Actual: 03/03/2016

Date of final study report

Planned: 31/12/2016

Actual: 09/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MEDA Pharma

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 overall research goal is to assess the effectiveness of the risk minimization measures for flupirtine 100 mg immediate-release capsules (flupirtine IR) by

evaluating to which extent these measures are implemented in daily practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective Chart Review (RCR), Post-authorization safety study (PASS)

Study drug and medical condition

Medical condition to be studied

Pain

Population studied

Short description of the study population

Physicians with at least one flupirtine IR treated patient in at least one of the three specified 6-month time periods in 2012, 2014 or 2015.

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

1.200

Study design details

Outcomes

To assess the overall compliance with the approved SmPC and the implemented risk minimization measures before (2012) and after the referral procedure and dissemination of the educational material (2015) by overall percentage of patients treated without compliance to the introduced risk minimization measures. To assess the overall compliance with the approved SmPC and the implemented risk minimization measures before (2012) and after the referral procedure (2014) by overall percentage of patients treated without compliance to the introduced riskminimization measures.To assess the extent of compliance.

Data analysis plan

Statistical analyses will be exploratory using descriptive and inferentialstatistics.

Documents

Study results

Abstract Flupirtine PASS 3300_Redacted.pdf (168.3 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

Local patient records

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