# 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

**PURI**

https://redirect.ema.europa.eu/resource/28844

---

**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

( **Study contact** )

[Dennis.Castor@mylan.com](mailto: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**

1200

# 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

## 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