Survey to Measure the effectiveness of the Mycamine Prescriber Checklist in the European Union

First published: 31/05/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/19727

EU PAS number

EUPAS13634

Study ID

19727

DARWIN EU® study

No

Study countries

☐ Czechia

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Poland
- [ ] Spain
- [ ] United Kingdom

Study description

This online survey aims to check the effectiveness of the Mycamine prescriber checklist on the prescribing of the product, and is a repeat of the study conducted in 2013. The first survey was conducted in 2013, and its protocol was agreed upon with the EMA in January 2013 (EMA/47969/2013). Astellas and EMA agreed on 23 July 2015 (EMEA/H/C/000734/II/0026) to repeat the survey using the same protocol.

Study status

Finalised

Research institutions and networks

Institutions

GfK Health

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Heike Tombrink

Study contact

heike.tombrink@gfk.com

Primary lead investigator

Heike Tombrink

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/01/2016

Actual: 25/01/2016

Study start date

Planned: 29/02/2016

Actual: 14/03/2016

Date of final study report

Planned: 29/07/2016

Actual: 08/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Mycamine Prescriber Checklist

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

1)To understand awareness and use of the Prescriber Checklist provided together with Mycamine® 2)To evaluate familiarity of physicians about measures of Risk Minimization Plan, the SmPC and other minimization tools like the Prescriber Checklist and the Administration and Monitoring Guide (indirect assessment).

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

Mycamine prescribers.

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

240

Study design details

Data analysis plan

Descriptive statistics only.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Online survey

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