NB-452: A cross-sectional survey to evaluate the effectiveness of the Mysimba® Physician Prescribing Checklist (PPC) among physicians in the European Union (EU)

First published: 16/08/2021

Last updated: 19/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42492

EU PAS number

EUPAS42491

Study ID

42492

DARWIN EU® study

No

Study countries

- [ ] Czechia
- [ ] Greece
- [ ] Hungary
- [ ] Norway
- [ ] Poland

Study description

The study is to assess the effectiveness of the PPC through evaluation of physician awareness and utilisation of the PPC, knowledge of the contraindications, warnings, precautions of Mysimba, knowledge of factors that may increase the risk of adverse reactions, and impact upon a physician's behaviour with respect to mitigating the risks in patients receiving Mysimba therapy.

Study status

Finalised

Research institutions and networks

Institutions

Ergomed

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Institution

Contact details

Study institution contact

Michael Kyle

Study contact

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Primary lead investigator

Michael Kyle

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/08/2020

Study start date

Actual: 25/03/2021

Date of final study report

Planned: 29/10/2021

Actual: 24/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Currax Pharmaceuticals LLC

Study protocol

NB-452 Protocol_FINAL.pdf(646.11 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The objective of the study is to evaluate physician receipt, knowledge, application and effectiveness in current clinical practice, of the Mysimba PPC.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

MYSIMBA

Study drug International non-proprietary name (INN) or common name

BUPROPION HYDROCHLORIDE

NALTREXONE HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(A08AA) Centrally acting antiobesity products

Centrally acting antiobesity products

Population studied

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

200

Study design details

Outcomes

Primary outcome: 85% of physicians whose correct response rate for the general PPC knowledge and risk-related questions (Questions 2-10) is at least 80%, or a score of 20 out of 25 possible points.

Data analysis plan

Categorical data will be summarised with frequencies and percentages. Continuous data will be summarised with the following descriptive statistics unless otherwise noted: number of observations, mean, standard deviation (SD), median, minimum, and maximum. Descriptive statistics will be performed on each survey question and pooled across all countries. The response rate for each question in the survey will be based on the total number of correct responses out of the total number of responses for that particular question. Responses to survey questions will also be summarised by demographics of respondents (country, medical specialty, years in practice, practice setting, and number of patients prescribed Mysimba). There will be no imputation for incomplete or missing data.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Surveys are conducted using SurveyMonkey

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

No