

# 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

### EU PAS number

EUPAS42491

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### Study ID

42492

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### DARWIN EU® study

No

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### Study countries

Czechia

Greece

Hungary

Norway

Poland

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### 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.

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### Study status

Finalised

## Research institutions and networks

### Institutions

Ergomed

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Michael Kyle mkyle@curraxpharma.com

Study contact

[mkyle@curraxpharma.com](mailto:mkyle@curraxpharma.com)

**Primary lead investigator**

Michael Kyle

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 10/08/2020

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**Study start date**

Actual: 25/03/2021

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**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

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **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

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##### **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

### Medicinal product name

MYSIMBA

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

BUPROPION HYDROCHLORIDE

NALTREXONE HYDROCHLORIDE

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### 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)
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### 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.

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## 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

### 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

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No