# Effectiveness of the Mysimba Physician Prescribing Checklist (PPC): Focus group to assess understanding, attitude, and behaviour for usage of the PPC and for key safety messages (NB-453 PPC focus groups)

**First published:** 01/03/2023

**Last updated:** 08/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS103748

**Study ID**

103749

**DARWIN EU® study**

No

**Study countries**

Czechia

Greece

Norway

**Study description**

This is a follow-up study to the NB-452 Physician Prescribing Checklist (PPC) survey study in which 71.3% (95%CI 64.9%, 77.1%) of Mysimba prescribers met the overall knowledge and understanding (KAU) criteria (primary outcome), which did not reach the pre-specified threshold of 85% for effectiveness of the PPC. Prior to developing a strategy for improving the awareness, usage and understanding of the Mysimba PPC, or making any modification to the risk minimisation strategy, it is necessary to conduct a root cause analysis of low awareness of the PPC as well as of incorrect responses to survey questions related to knowledge and understanding of selected key safety messages. This focus group study will be conducted to help determine the adequacy of the Mysimba PPC, and potentially guide strategies to improve the understanding of key safety messages described in the EU RMP for Mysimba.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Currax Pharmaceuticals

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

**Last updated:** 01/02/2024

Institution

# Contact details

**Study institution contact**

Michael Kyle mkyle@curraxpharma.com

Study contact

mkyle@curraxpharma.com

**Primary lead investigator**

Michael Kyle

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 14/12/2022

Actual: 14/12/2022

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**Study start date**

Planned: 31/03/2023

Actual: 31/03/2023

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**Data analysis start date**

Planned: 30/06/2023

Actual: 30/06/2023

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**Date of final study report**

Planned: 30/09/2023

Actual: 23/10/2023

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Orexigen Therapeutics/Currax Pharmaceuticals LLC

## Study protocol

NB-453 Focus Group Protocol_05 DEC 2022_FINAL.pdf (512.8 KB)

## 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)

## Other study registration identification numbers and links

NB-453, EMEA/H/C/003687/II/0054

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

To identify factors that could explain the low awareness and usage of the PPC seen in Study NB-452 as well as the inadequate responses to selected questions on key safety messages.

## Study Design

**Non-interventional study design**

Cohort

Other

**Non-interventional study design, other**

Online focus groups

## Study drug and medical condition

**Medicinal product name**

MYSIMBA

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

BUPROPION HYDROCHLORIDE

NALTREXONE HYDROCHLORIDE

**Anatomical Therapeutic Chemical (ATC) code**

(A08AA62) bupropion and naltrexone

bupropion and naltrexone

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**Medical condition to be studied**

Overweight

Obesity

# Population studied

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

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**Estimated number of subjects**

24

# Study design details

**Outcomes**

Among Mysimba prescribers, the study aims to determine prescribers' awareness and usage of the PPC, and to understand prescribers' attitudes and agreement with the key safety messages in the PPC. Based on feedback obtained during conduct of focus groups, it will be determined whether changes to the PPC are necessary to improve awareness and understanding of key safety messages.

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**Data analysis plan**

As qualitative research, there are no endpoints. Instead, themes will be sought with the aim of saturation (i.e. no more new themes emerge from discussions). Thematic analysis will be used, which involves searching across discussion verbatim and notes in order to identify, organize, describe repeated patterns. The verbatim of the focus group discussions will be transcribed and analyzed along with field notes constructed by the moderator and assistant moderator, and any notes extracted from the debriefing meeting. Coding will be conducted using a qualitative data analysis software program. Analysis will include systematic coding using constant comparison analysis. Codes will be reviewed to identify themes, opinions, and beliefs that are recurrent (referred to as nodes). Coding will be deductive (pre-set coding scheme, based on hypotheses regarding less well understood safety messages) and inductive (nodes will be generated while examining data). Significant nodes will be grouped.

## Documents

**Study results**

nb-453-csr_23 OCT 23.pdf (901.13 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**

Mysimba-prescribing physicians in 3 countries will be invited to participate in online focus groups.

## 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