# Use of Nalmefene (Selincro®) in European databases: Cohort design using longitudinal electronic medical records or claims databases

**First published:** 27/07/2016

**Last updated:** 09/10/2025

Study    Finalised

## Administrative details

**EU PAS number**

EUPAS14083

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**Study ID**

16907

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**DARWIN EU® study**

No

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**Study countries**

☐ Germany

☐ Sweden

☐ United Kingdom

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**Study description**

Databases analyses in several European countries have been proposed to investigate patterns of use of Selincro® in real clinical practice taking into account the important risks and missing information documented in the RMP.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### H. Lundbeck

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

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

Institution

# Contact details

**Study institution contact**

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Study contact

LundbeckClinicalTrials@lundbeck.com

**Primary lead investigator**

# Email contact via H. Lundbeck A/S Email contact via H. Lundbeck A/S

<span style="border:1px solid #1a4480; border-radius:20px; padding:4px 12px;">**Primary lead investigator**</span>

## Study timelines

**Date when funding contract was signed**

Planned: 15/11/2013

Actual: 15/07/2013

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**Study start date**

Planned: 01/08/2016

Actual: 01/08/2016

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**Data analysis start date**

Planned: 02/08/2016

Actual: 02/08/2016

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**Date of interim report, if expected**

Planned: 31/07/2017

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**Date of final study report**

Planned: 28/06/2019

Actual: 21/02/2021

## Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

H. Lundbeck A/S

# Study protocol

15649A version 3 0 09 MAR 2015 Abstract for Encepp .pdf (41.79 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)

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Main study objective:**

The primary objective of the database analysis is to describe the use of Selincro® in clinical practice, particularly in different sub-populations.

# Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Name of medicine**

SELINCRO

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

NALMEFENE

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**Anatomical Therapeutic Chemical (ATC) code**

(N07BB05) nalmefene

nalmefene

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**Medical condition to be studied**

Alcohol use

# 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**

2000

# Study design details

**Outcomes**

age, gender, pregnancy, proportion of patients with increased (>3xULN) ALAT or ASAT, proportion of patients with psychiatric or somatic comorbidity, proportion of patients with history of seizure, the proportion of patients with concurrent prescription of CNS active medication, The use of Selincro® over more than one year and the occurrence of overdose.

The use of Selincro® in patients outside the indication defined in the SmPC.

**Data analysis plan**

In this non comparative study, only descriptive statistics will be used. Consequently, all variables will be summarised using descriptive techniques: summary statistics (mean, standard deviation, median, inter-quartile range, minimum and maximum values) will be presented for continuous variables, and counts and percentages will be presented for categorical and binary variables. Missing values will be displayed.

# Documents

**Study publications**

[Safety and Persistence of Nalmefene Treatment for Alcohol Dependence. Results f...](#)

# 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 source(s)**

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

**Data sources (types)**

[Administrative healthcare records (e.g., claims)](#)

[Electronic healthcare records (EHR)](#)

## 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