

# Use of Selincro® and impact on usual practice (USE-PACT)

**First published:** 15/12/2015

**Last updated:** 23/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11854

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### Study ID

49889

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

Selincro® (nalmefene) has obtained European market authorisation “for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and

who do not require immediate detoxification". The French health authorities have requested an evaluation on real-life conditions of Selincro® use and its impact on morbidity. In response, a French prospective cohort including 1000 patients initiating Selincro® followed during 1 year using a random sample of general practitioners, psychiatrists, and physicians in specialised structures has been developed. The main objective is to evaluate the evolution of alcohol consumption at 1 year in patients initiating Selincro®. The secondaries are to describe prescribers characteristics, initial demographic, clinical, biological characteristics of patients, patient support, notably psychosocial, at start and during treatment, characteristics of Selincro® during the study period, the frequency of adverse effects during Selincro® treatment. Each participating physician should, during 4-month period, include in cohort all patients for whom he/she initiates Selincro® and fulfilling the eligibility criteria, and record in a non-inclusion register patients for whom Selincro® is initiated and not included in cohort. The physician will follow the patients with a clinical evaluation at 1, 3, 6, 9 and 12 months performed during usual follow-up consultations. In parallel, each patient will complete a self-administered questionnaire at the same points. Patients declared as lost-to-follow-up and, failing that, his/her general practitioner will be contacted in order to fill-out a "last known status questionnaire". For patients who could not be reached, vital status will be investigated using the INSEE/INSERM centralised procedure defined by decree. The representativeness of the cohort will be evaluated by an analysis in a representative French health insurance database.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

# Bordeaux PharmacoEpi, University of Bordeaux

 France

**First published:** 07/02/2023

**Last updated:** 08/12/2025

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

Not-for-profit

ENCePP partner

Multiple centres: 180 centres are involved in the study

## Contact details

### Study institution contact

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Study contact

[patrick.blin@u-bordeaux.fr](mailto:patrick.blin@u-bordeaux.fr)

### Primary lead investigator

Nicholas Moore

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/07/2015

Actual: 14/10/2015

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**Study start date**

Planned: 01/09/2015

Actual: 23/02/2016

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**Date of final study report**

Planned: 01/12/2017

Actual: 10/07/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Lundbeck France

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation  
Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

To evaluate the evolution of alcohol consumption at one year in patients initiating Selincro® in usual practice.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N07BB05) nalmefene  
nalmefene

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## **Medical condition to be studied**

Alcohol abuse

## **Population studied**

### **Short description of the study population**

Adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and who do not require immediate detoxification initiated treatment with Selincro® (nalmefene).

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### **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**

1000

## **Study design details**

### **Outcomes**

The evolution of alcohol consumption at 1 year will be defined as the relative evolution of Total Alcohol Consumption (TAC) between inclusion and end of follow-up at 1 year. The TAC (g/day) is equal to the number of standard drinks consumed in previous week by patient multiplied by a factor of ten (one standard drink corresponding to about 10g of alcohol), then divided by 7 (days

number of week). At the different times of follow-up (1, 3, 6, 9 and 12 months) the evolution of alcohol consumption will be evaluated with respect to inclusion day in terms of: relative and absolute evolution of TAC and Heavy Drinking Days (HDD, number of days with a high consumption of alcohol), at least 70% reduction in TAC, change in the alcohol consumption risk level according to the WHO.

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### **Data analysis plan**

Statistical analysis will be performed after database lock using SAS® software. The representativeness of the cohort in terms of patient characteristics will be evaluated by an analysis in a representative French health insurance database, the EGB (Echantillon Généraliste de Bénéficiaires). Statistical analysis will provide a description of : the total population, and according to prescriber specialty, and previous medicinal treatment, the treated patient characteristics, the evolution in alcohol consumption, the follow-up, Selincro® treatment, and adverse events.

## 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**

Prospective patient-based data collection

## **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