# XYREM EU-RMP: Effectiveness Assessment Protocol of Educational Materials

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### Administrative details

EU PAS number
EUPAS15024
Study ID
29341
DARWIN EU® study
No
Study countries
Belgium
Germany
Italy
Spain
Sweden
United Kingdom

#### **Study description**

The overall research question is to evaluate the effectiveness of the educational material risk minimization measures (RMMs) being implemented in the EU to mitigate the important identified risks of respiratory and central nervous system (CNS) depression, depression and suicidality, abuse and misuse of XYREM, diversion and criminal use, overdose, dependency/withdrawal, and interactions of XYREM with alcohol, the important potential risks associated with sodium overload, in patients prescribed XYREM.

#### **Study status**

Finalised

### Contact details

### **Study institution contact**

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent is not available. clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

### **Primary lead investigator**

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent is not available.

Primary lead investigator

## Study timelines

#### Date when funding contract was signed

Actual: 07/12/2015

#### **Study start date**

Actual: 01/01/2016

#### Data analysis start date

Planned: 29/12/2017

#### **Date of final study report**

Planned: 14/04/2019

Actual: 09/04/2019

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

UCB BioPharma SPRL

## Study protocol

NA0001 PASS Amendment 4 Protocol-final-redacted.pdf (856.91 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

# Methodological aspects

# Study type

# Study type list

#### **Study topic:**

Human medicinal product

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### Data collection methods:

Primary data collection

### Main study objective:

Evaluate the effectiveness of the educational material RMMs implemented in the EU to mitigate the important identified risks of respiratory and CNS depression, depression/suicidality, abuse/misuse of XYREM, diversion/criminal use, overdose, dependency/withdrawal, and interactions of XYREM with alcohol, the important potential risks associated with sodium overload in patients prescribed XYREM.

### Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Survey

# Study drug and medical condition

#### **Medicinal product name**

**XYREM** 

# Population studied

#### Short description of the study population

XYREM prescribers from Belgium, Germany, Italy, Spain, Sweden, and the UK to whom the XYREM educational materials were sent.

Physicians were required to meet the following inclusion criterion:

1. Must have been included on the XYREM RMP educational materials mailing list

#### Age groups

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

#### **Estimated number of subjects**

200

## Study design details

#### **Outcomes**

Proportion of respondents providing a correct response for each individual question consistent with the XYREM summary of product characteristics (SmPC).

#### Data analysis plan

The primary outcome of the survey is the proportion of prescribers providing a correct response for each individual question in the key risk messages consistent with the XYREM EU SmPC. This is computed as the proportion of prescribers who correctly respond to the individual survey questions concerning the appropriate dosing and important identified risks of XYREM as described in the XYREM SmPC. The proportion responding correctly will be tabulated separately for each item in the survey instrument. Point estimates for the proportion with correct responses, and associated 95% confidence intervals, will be calculated for each question. In the case of multiple choice questions, the number and proportion of prescribers reporting each response will also be provided. Information obtained from the survey will be reported as descriptive statistics for the survey administration, survey population, and the survey questions.

### **Documents**

#### Study results

CSR\_UCB\_Xyrem Online Survey NA0001 PASS Study-final-redacted.pdf (779.89 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

Surveys will be used to assess the effectiveness of the risk minimisation methods available to prescribers

## Use of a Common Data Model (CDM)

### **CDM** mapping

No

# Data quality specifications

#### **Check conformance**

Unknown

### **Check completeness**

Unknown

#### **Check stability**

### **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

Unknown