XYREM EU-RMP: Effectiveness Assessment Protocol of Educational Materials

First published: 05/09/2016

Last updated: 02/07/2024

Study Finalised

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)?

EU RMP category 3 (required)

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

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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

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown