Post-Authorization Safety Study to Assess the Effectiveness of the Newly Implemented Risk Minimization Measures for Topiramate: HCP and Patient Knowledge and Behavior Survey

First published: 06/11/2025

Last updated: 26/11/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000806

Study ID

1000000806

DARWIN EU® study

No

Study countries

France

Germany

Poland

Spain

Sweden

United Kingdom

Study description

Cross-sectional, multinational, and non-interventional on-line survey to assess the impact of the newly implemented Risk Minimization Measures (RMMs) on the knowledge and self-reported behaviour of HCPs involved in prescription, dispensing, and/or consultation of topiramate mono-component products and of Women of Childbearing Potential (WOCBP) treated with topiramate mono-component products for migraine and/or epilepsy in the EU and UK.

Study status

Ongoing

Research institutions and networks

Institutions

Syneos Health

United Kingdom

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Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 20/09/2024

Actual: 20/09/2024

Study start date

Planned: 18/03/2026

Actual: 10/06/2026

Data analysis start date

Planned: 19/07/2027

Date of final study report

Planned: 13/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Topiramate Safety Consortium of MAHs, led by Janssen

Study protocol

REDACTED_Protocol-FD-PCSESPA0008-1159530_2106154.pdf (4.43 MB)

Protocol_abstract_Topiramate PASS_7054980_SURVEY.pdf (238.2 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/A-31/1520

Other study registration identification numbers and links

PCSESPA0008

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

Study design:

Cross-sectional, multinational, non-interventional survey among HCPs involved in prescription, dispensing, and/or consultation of topiramate mono-component products and WOCBP (≥13 to ≤49 years of age) exposed to it for migraine and/or epilepsy in 6 European countries (5 EU member states and the UK)

Main study objective:

To assess the impact of the newly implemented RMMs on the knowledge and self-reported behavior of HCPs who prescribe topiramate mono-component products and of patients treated with topiramate mono-component products in the EU and UK.

To assess the awareness of:
WOCBP treated with topiramate mono-component products with respect to the receipt of the Educational Materials (EMs).
HCPs with respect to the receipt of/access to Direct Healthcare Professional Communications (DHPC) and EMs for topiramate mono-component products.

To assess the knowledge of:
WOCBP treated with topiramate mono-components products, with respect to risks associated with use of topiramate during pregnancy and measures to prevent exposed pregnancies.
HCPs with respect to risks associated with use of topiramate during pregnancy and measures to prevent pregnancies among WOCBP exposed to topiramate mono-component products.

To assess the self-reported behavior of:
WOCBP treated with topiramate mono-component products, with respect to measures to prevent exposed pregnancies.
HCPs with respect to measures to prevent pregnancies among WOCBP exposed to topiramate mono-component products.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Multinational survey

Study drug and medical condition

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

TOPIRAMATE

Anatomical Therapeutic Chemical (ATC) code

(N03AX11) topiramate

topiramate

Medical condition to be studied

Epilepsy

Migraine

Population studied

Short description of the study population

The target population of the survey will be composed of women of childbearing potential (WOCBP) who are treated with topiramate and HCPs grouped into three categories: 1) those who prescribe topiramate, 2) those who dispense topiramate, and 3) those who consult with or see patients receiving topiramate, in the targeted countries.

Age groups

- **Paediatric Population (< 18 years)**
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

1.500

Study design details

Outcomes

The HCP and patient surveys will begin with screening questions, followed by items assessing awareness, knowledge, and behavior. For each dimension, the proportion of participants who correctly respond to at least 80% of the relevant questions will be calculated.

Data analysis plan

Data from patients and HCPs will be analyzed separately, with all analyses being descriptive. The patient dataset will be analyzed by indication, while the HCP will be analyzed by (1) HCP category and (2) medical specialty. The main analysis will be conducted for all countries combined, for all EU countries (excluding the UK), and for each individual country.

Within the HCP and patient datasets, a derived variable in the form of a score summarizing all responses at individual participant level will be created for each of the main dimensions of the survey (awareness, knowledge, and behavior). The individual score will be calculated as the proportion of correct responses to all questions within each domain. Success for each dimension is defined as a score of at least 80%.

For each dimension, the number and proportion of participants who have a score of at least 80% will be calculated. Success for each dimension is defined as having at least 80% of successful participants.

At a study level (i.e., all dimensions combined), the newly implemented RMMs will be considered satisfactory if the behavior outcome and at least one of the two other outcomes (awareness and/or knowledge) are equal to or above the defined threshold of 80% of successful participants.

Data management

Data sources

Data source(s), other

The data source will be on-line questionnaires completed by HCPs and patients (or parents/caregivers) who have passed the screening and who have given consent.

Data sources (types)

Other

Patient surveys

Data sources (types), other

Surveys of HCPs, including general practitioners (GPs), specialists in internal medicine, specialists involved in the management of epilepsy and/or migraine (e.g., neurologists, general pediatricians, neuro-pediatricians, and psychiatrists), obstetricians/gynecologists (OB/GYNs), midwives, and pharmacists.The HCP specialties included in the survey may vary by participating country.

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