A Drug Utilisation Study of Qsiva for Weight Management: A Postmarketing Cohort Database Study in Denmark, Finland, Norway, and Sweden

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000883

Study ID

1000000883

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Finland
- ☐ Norway

Sweden

Study description

Qsiva® (Vivus, B.V.) is a fixed-dose combination of phentermine hydrochloride and topiramate. According to the summary of product characteristics (SmPC), Qsiva, as an adjunct to a reduced-calorie diet and physical activity, is indicated for weight management in adult patients with an initial body mass index (BMI) of ≥30 kg/m2 (obese) or ≥27 kg/m2 (overweight) with weight-related comorbidities such as hypertension, type 2 diabetes, or dyslipidaemia. Qsiva was first approved for use in the Nordic countries in 2021 and later received approval from other European countries through de-centralised procedures. Qsiva is also approved for use in the United States and the Republic of Korea (as Qsymia®). Warnings and precautions are included for the use of Qsiva in patients with cardiovascular disease and patients with psychiatric disorders, including mood disturbances and suicidal ideation. This drug utilisation study aims at describing important characteristics of the patient population initiating the use of Qsiva in Denmark, Finland, Norway, and Sweden and demonstrating that the patient characteristics are consistent with the labelled indication for Qsiva.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Erik Joas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2023

Actual: 15/09/2023

Study start date

Planned: 17/11/2025

Actual: 17/11/2025

Data analysis start date

Planned: 23/03/2026

Date of final study report
Planned: 30/09/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The study is funded by VIVUS LLC.

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)

Other study registration identification numbers and links

Protocol identification number: OB-907

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

This will be a multi-country, non-interventional cohort study using secondary data to evaluate the effectiveness of risk minimisation measures regarding the risks of cardiovascular and psychiatric conditions among patients prescribed Qsiva.

Main study objective:

(1) To describe demographic and baseline characteristics of patients initiating Qsiva

(2) To evaluate Qsiva use inconsistent with specified warnings and precautions and inconsistent with contraindication listed below:

– Qsiva use inconsistent with warnings and precautions:

a) Use in patients with a history of recurrent major depression, bipolar disorder, or psychosis, or in patients with current depression of moderate or worse severity or in patients with suicidal ideation and behaviour

b) Use in patients with a recent myocardial infarction or in other patients at high cardiovascular risk including those with a history of advanced cardiovascular disease (e.g., recent stroke, malignant arrhythmias, congestive

heart failure)

– Qsiva use inconsistent with contraindication:

a) Use in patients receiving treatment with monoamine oxidase inhibitors (MAOIs)

b) Other medicinal products intended for weight loss

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Qsiva

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

PHENTERMINE HYDROCHLORIDE

TOPIRAMATE

Anatomical Therapeutic Chemical (ATC) code

(A08AA51) phentermine and topiramate

phentermine and topiramate

Medical condition to be studied

Psychiatric symptom

Cardiovascular symptom

Obesity

Population studied

Short description of the study population

The study will include all individuals with at least 5 years of available information in the data source before receiving a first dispensing of Qsiva during the study period (Dec 2024 up to Dec 2031 [longest study period for patient inclusion]).

Age groups

- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

1000

Study design details

Setting

The study is planned to be conducted 4 European countries (Denmark, Finland, Norway, and Sweden) in which Qsiva is approved. National health registers, which collect data from daily practice in the study countries, will be used to study the patient characteristics and prescribing practices in the real world.

Comparators

No comparator.

Outcomes

Patient characteristics, indicators of inappropriate prescribing (e.g., selected cardiovascular conditions and psychiatric conditions, contraindicated medications), indicators of appropriate prescribing (i.e., hypertension and hypertensive heart disease, type 2 diabetes, dyslipidaemia).

Data analysis plan

Exposure to Qsiva will be identified through Anatomical Therapeutic Chemical (ATC) codes based on dispensing prescriptions. Daily dose of Qsiva will be assessed. Characteristics of patients exposed to Qsiva will be assessed at baseline, including demographic variables (e.g., sex, age), lifestyle variables, indicators of inappropriate prescribing (e.g., selected cardiovascular conditions and psychiatric conditions, contraindicated medications), indicators of appropriate prescribing (i.e., hypertension and hypertensive heart disease, type 2 diabetes, dyslipidaemia), other comorbidities, other comedications, and prescriber information. The distributions of all study variables will be calculated and reported. The distribution of characteristics will be calculated and displayed as counts and percentages for categorical variables. For continuous variables, means, standard deviations, medians, first quartiles, third quartiles, first percentile and 99th percentile will be calculated, as appropriate.

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)

Danish Health Care Registries

Norwegian Health Registers

Data source(s), other

Finnish Health Registers; Swedish Health Registers

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown

Data characterisation moment

after data extraction