LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Qsiva
# phentermine hydrochloride, topiramate

# SE/H/1963/01-04/DC

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# Summary Public Assessment Report

Qsiva
phentermine hydrochloride, topiramate

Modified-release capsule, hard, 7,5 mg/46 mg, 3,75 mg/23 mg, 15 mg/92 mg, 11,25 mg/69 mg

This is a summary of the public assessment report (PAR) for Qsiva. It explains how Qsiva was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Qsiva.

For practical information about using Qsiva, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Qsiva and what is it used for?

Qsiva is used in addition to reduced calorie diet and bodily activity to assist adults to lose weight and keep weight down. It is recommended for:

- obese patients with body mass index (BMI) of 30 kg/$m^2$ and over, or
- overweight patients with body mass index of 27 kg/$m^2$ or over, and weight-related health problems such as high blood pressure, diabetes or abnormal blood fat levels

## How does Qsiva work?

Qsiva contains two active substances called phentermine and topiramate, which work together to reduce your appetite. Taking both together better aids weight loss than just taking one by itself.

## How is Qsiva used?

The pharmaceutical form of Qsiva is hard capsules with modified release, the capsules are intended for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

## What benefits of Qsiva have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Qsiva is effective as an adjunct to a reduced-calorie diet and physical activity, and is indicated for weight management in adult patients with an initial Body Mass Index (BMI) of

- ≥30 kg/$m^2$ (obese), or
- ≥27 kg/$m^2$ (overweight) with weight-related co-morbidities such as hypertension, type-2 diabetes or dyslipidaemia

## What are the possible side effects of Qsiva?

For the full list of all side effects reported with Qsiva, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

## Why is Qsiva approved?

It was noted that the effect of Qsiva in the 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 co-morbidities such as hypertension, type-2 diabetes or dyslipidaemia, was significantly better than treatment with placebo, this being showed in placebo controlled studies.

Studies has also shown a greater effect when using both active substances together, than by using either one solely.

Therefore, the Medical Products Agency in Sweden decided that Qsiva's benefits are greater than its risks and recommended that it be approved for use.

Qsiva has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Qsiva?"

## What measures are being taken to ensure the safe and effective use of Qsiva?

A risk management plan has been developed to ensure that Qsiva is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Qsiva, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

The company is obliged to provide some additional risk management measures, such as educational material (prescriber guide and checklist/patient guide) to address pregnancy prevention, increased heart rate, psychiatric disorders, and cognitive disorders.

The company must also carry out further studies to show the effectiveness of these additional risk management measures.

## Other information about Qsiva

The full PAR for Qsiva can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Qsiva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-03.