

Package leaflet: Information for the patient

Qsiva 3.75 mg/23 mg hard modified-release capsules
Qsiva 7.5 mg/46 mg hard modified-release capsules
Qsiva 11.25 mg/69 mg hard modified-release capsules
Qsiva 15 mg/92 mg hard modified-release capsules

phentermine/topiramate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Qsiva is and what it is used for
2. What you need to know before you take Qsiva
3. How to take Qsiva
4. Possible side effects
5. How to store Qsiva
6. Contents of the pack and other information

1. What Qsiva is and what it is used for

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.

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/m² and over, or
- overweight patients with body mass index of 27 kg/m² or over, and weight-related health problems such as high blood pressure, diabetes or abnormal blood fat levels

2. What you need to know before you take Qsiva

Do not take Qsiva if you are:

- allergic to phentermine, topiramate or any of the other ingredients of this medicine (listed in section 6)
- allergic to medicines called sympathomimetic amines, which are medicines to treat asthma, blocked nose or eye disorders
- pregnant, or a woman who is able to become pregnant unless you are using highly effective contraception (see section 'Pregnancy and breastfeeding' for further information). You should talk to your doctor about the best kind of contraception to use while you are taking Qsiva. Make sure you read the patient guide that you will receive from your doctor. A patient card is provided with the Qsiva package to remind you of the risks in pregnancy.
- taking medicines called monoamine oxidase inhibitors or have taken within the last 14 days, such as

- iproniazid: used to treat depression
- isoniazid: used to treat tuberculosis
- phenelzine, tranylcypromine: used to treat depression or Parkinson's disease
- taking other medicines to aid weight loss

Warnings and precautions

Talk to your doctor before or during taking Qsiva if you are/have:

- a woman who is able to become pregnant . Qsiva can harm an unborn child when taken during pregnancy. Highly effective contraception (birth control) must be used during your treatment and for at least 4 weeks after the last Qsiva dose. See section 'pregnancy and breastfeeding' for further information.
- pregnant: Qsiva can harm an unborn child when taken during pregnancy.
- a mood disorder or depression, or have had in the past
Qsiva may worsen these conditions. Your doctor will monitor you closely if you have a history of these conditions. Inform your doctor immediately if you notice any unusual changes in mood or behaviour. Qsiva is not recommended in patients with:
 - a history of recurrent major depression
 - periods of depression and periods of abnormally elevated mood called bipolar disorder
 - psychosis
 - current depression of moderate or worse severity
- had suicidal thoughts or have attempted suicide
Qsiva may increase the occurrence of suicidal thoughts. Inform your doctor immediately if you notice suicidal ideation.
- heart problems or a blood vessel disease
Qsiva can cause an increase in your heart rate. Regular measurement of resting heart rate by the doctor is recommended for all patients during treatment.
Inform your doctor if you experience racing heartbeat while at rest during Qsiva treatment.
Qsiva use is not recommended in patients with:
 - a heart attack within the last 6 months
 - high risk of heart and blood circulation problems, including those with advanced diseases, such as a stroke within the last 3 months, aggressive irregular heartbeat, certain heart failures
- had a kidney stone, or one of your biological relatives has had a kidney stone, or you have a high blood calcium level
Qsiva may increase the risk of developing kidney stones. Therefore, it is recommended that all patients taking Qsiva **drink plenty of water** each day.
- acute eye problems
If you have sudden worsening of vision or blurred eyesight, or eye pain, stop taking Qsiva and contact your doctor or pharmacist immediately. These effects may be signs of eye diseases, such as short-sightedness or increased eye pressure.
- too much acid in your blood
Qsiva can increase the acid level in the blood. Your doctor may want to measure the amount of acid and bicarbonate in your blood regularly and may reduce your dose or stop Qsiva therapy if needed.
- reduced kidney or liver function
Qsiva is not recommended for patients with severely reduced liver function, end-stage kidney disease or those on dialysis.
- an overactive thyroid gland
Qsiva is not recommended in patients with overactive thyroid gland.

The active substance phentermine may increase your energy or level of excitement and therefore may have the potential for abuse and dependence.

Children and adolescents

Qsiva is not recommended for children and adolescents under 18 years.

Other medicines and Qsiva

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Qsiva and tell your doctor if you are taking:

- other medicines to help you lose weight
- medicines called monoamine oxidase inhibitors, or have taken those within the last 14 days, such as
 - iproniazid: used to treat depression
 - isoniazid: used to treat tuberculosis
 - phenelzine, tranylcypromine: used to treat depression or Parkinson's disease

Please also tell your doctor or pharmacist if you are taking:

- another medicine containing phentermine or topiramate
Qsiva is not recommended as a substitute for these medicines.
- hormonal contraceptives
The possibility of decreased contraceptive efficacy and irregular bleeding may occur when additionally taking Qsiva with hormonal contraceptives. Contraceptive efficacy can be reduced even in the absence of bleeding. An additional barrier method of contraception such as a condom or a pessary/diaphragm should be used. You should talk to your doctor about the best kind of contraception to use while you are taking Qsiva.
Irregular bleeding may occur. In this case, continue taking the hormonal contraceptives and inform your doctor.
- medicines that reduce alertness, such as
 - medicines to treat epilepsy or to sedate
 - medicines which calm, induce sleep or relax muscles such as diazepam
 - other sleep-inducing medicines
- medicines to increase water output through your kidneys, such as hydrochlorothiazide
It is recommended that the doctor monitors your blood potassium level when taking so-called non-potassium sparing diuretics.
- medicines to treat epilepsy, such as phenytoin, carbamazepine, valproic acid
- alfentanil: a painkiller used during an operation with anaesthetics
- fentanyl: a strong painkiller
- cyclosporine: a medicine to suppress the immune system, treat severe skin diseases and severe eye or joint inflammation
- dihydroergotamine, ergotamine: a medicine to treat migraine
- tacrolimus: a medicine to prevent transplant rejection and treat continuous or recurrent, non-contagious skin inflammation with severe itching
- sirolimus: a medicine to prevent transplant rejection
- everolimus: a medicine to treat cancer
- lithium, imipramine, moclobemide, St John's wort: medicines to treat depression
Monitoring the lithium level is recommended during treatment with Qsiva.
- pimozide: a medicine to treat mental disorders
- digoxin: a medicine to treat heart weakness and irregular heartbeat
- quinidine: a medicine to treat irregular heart rhythm
- proguanil: a medicine to treat and prevent malaria
- omeprazole: a medicine which reduces the release of stomach acid
- medicines called carbonic anhydrase inhibitors, such as
 - zonisamide: to treat epilepsy
 - acetazolamide: to treat increased eye pressure, abnormal retention of fluid, breathing problems, mountain sickness, epilepsy

- dichlorphenamide: to treat periodic paralysis
- medicines to treat diabetes such as pioglitazone, metformin, glibenclamide, insulin
Regular monitoring of your blood sugar level is recommended when taking Qsiva during treatment with one of these medicines. It is also recommended that the doctor regularly measures your bicarbonate level when taking metformin.

Qsiva with alcohol

Avoid drinking alcohol during treatment with Qsiva, as alcohol may increase the risk of side effects.

Pregnancy and breast-feeding

- **Pregnancy**

Important advice for women who are able to become pregnant

If you are a woman who is able to become pregnant, talk to your doctor about other possible treatments. Visit your doctor to review your treatment and discuss the risks at least once a year.

Do not take this medicine if you are **pregnant**

You must not use this medicine if you are a woman who is able to become pregnant unless you are using highly effective contraception.

Pregnancy testing should be performed before starting treatment with Qsiva in a woman who is able to become pregnant.

The risks of topiramate (one of the active substances of Qsiva, also used to treat epilepsy) when taken during pregnancy:

- Topiramate can harm and reduce growth of the foetus when taken during pregnancy. Your child has a higher risk for birth defects. In women who take topiramate, around 4 - 9 children in every 100 will have birth defects. This compares to 1-3 children in every 100 born to women who do not have epilepsy and do not take an antiepileptic treatment. Particularly, cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth) have been observed. Newborn boys may also have a malformation of the penis (hypospadias). These defects can develop early in pregnancy, even before you know you are pregnant.
- If you take Qsiva during pregnancy, your child may have a 2- to 3-fold higher risk for autism spectrum disorders, intellectual disabilities, or developing attention deficit hyperactivity disorder (ADHD) compared with children born to women with epilepsy not taking antiepileptic medication.
- If you take Qsiva during pregnancy, your child may be smaller and weigh less than expected at birth. In one study, 18 % of children of mothers taking topiramate during pregnancy were smaller and weighed less than expected at birth, while 5 % of children born to women without epilepsy and not taking antiepileptic medication were smaller and weighed less than expected at birth.

Need for contraception in women who are able to become pregnant:

- If you are a woman who is able to become pregnant, you should talk to your doctor about other possible treatments instead of Qsiva. If the decision is made to use Qsiva, you must use highly effective contraception during your treatment and for at least 4 weeks after the last Qsiva dose.
- One highly effective contraception (such as an intrauterine device) or two complementary contraceptives such as birth control pill together with a barrier method of birth control (such as a condom or pessary/diaphragm) must be used. Talk to your doctor about what contraception that is most appropriate for you.
- If you are taking hormonal contraceptives, there is the possibility of reduced effectiveness of the hormonal contraceptives due to topiramate. Therefore, an additional barrier contraceptive method should be used. Tell your doctor if you experience irregular bleeding.

- Stop taking Qsiva immediately and tell your doctor if you miss a menstrual period or suspect you are pregnant.

If you wish to become pregnant while taking Qsiva:

- Schedule an appointment with your doctor.
- Do not stop using your contraception until you have discussed this with your doctor.

If you have become pregnant or think you may be pregnant while taking Qsiva:

- Schedule an urgent appointment with your doctor.
- Stop taking Qsiva immediately and tell your doctor.
- The doctor will counsel you about the risks of Qsiva during pregnancy.

Make sure you read the patient guide that you will receive from your doctor.

A patient card is provided with the Qsiva package to remind you of topiramate risks in pregnancy.

- **Breast-feeding**
Breast-feeding is not recommended when taking Qsiva, as the medicine can pass into breast milk. Your doctor will decide whether to suspend breast feeding or to abstain from Qsiva.

Driving and using machines

Avoid driving or using machines during treatment with Qsiva if your ability to react is reduced.

Drowsiness, dizziness, visual disturbances and blurred vision have been reported when taking one of the contained active substances. Wait until you know how Qsiva affects you before trying any of these activities.

Qsiva 3.75 mg/23 mg hard modified-release capsules

Qsiva contains sucrose

Qsiva contains a small amount of a type of sugar called sucrose. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Qsiva 7.5 mg/46 mg, 11.25 mg/69 mg and 15 mg/92 mg hard modified-release capsules

Qsiva contains sucrose, tartrazine and Sunset Yellow FCF

Qsiva contains a small amount of a type of sugar called sucrose. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The colourings tartrazine and Sunset Yellow FCF may cause allergic reactions.

3. How to take Qsiva

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Qsiva treatment should be started and supervised by a doctor experienced in the treatment of weight management. Women who are able to become pregnant should visit their doctor to review their treatment at least once a year.

Your doctor determines the right dose for you.

Your doctor will **start** your **treatment** with a low dose of 1 capsule Qsiva 3.75 mg/23 mg once daily for 14 days. There may be reasons for your doctor to keep this dose throughout your treatment, for example if you have a kidney or liver disease. If you have kidney disease your doctor may also start with a low dose every other day, instead of daily.

The usual recommended dose is 1 capsule Osiva 7.5 mg/46 mg once daily after 14 days. You stay on this dose for approximately 3 months. If you have not lost minimum 5% of your starting body weight after this time your doctor may stop treatment.

If you have lost at least 5% and you tolerate the treatment well your doctor may recommend continue treatment using the same dose. If your body weight remains high and your doctor recommends a higher dose, you will be given 1 capsule Qsiva 11.25 mg/69 mg once daily for 14 days. Afterwards, the dose can be increased to 1 capsule Qsiva 15 mg/92 mg once daily. If discontinuing treatment from this high dose, it is recommended to do this gradually by taking a dose every other day for at least 1 week prior stopping treatment.

Your doctor will also want to monitor your progress carefully. Therefore, attend all appointments given to you.

Follow all the diet, exercise and lifestyle changes recommended by your doctor or dietician.

Your doctor may recommend that you take a daily multivitamin supplement.

Method of use

Swallow the capsules whole, once daily in the morning, with a glass of water or other sugar-free drink. Do not crush or chew them. You can take the capsules with or without food.

If you take more Qsiva than you should

Talk to a doctor or go to a hospital straight away if this occurs. Take the medicine pack with you.

If you forget to take Qsiva

- If you forget a dose in the morning you can still take it up to the middle of the day.
- Skip the missed dose if you do not remember it until the afternoon. Then wait until the next morning to take your next daily dose as usual.
- Do not take a double dose to make up for a forgotten dose.
- If you have missed more than 7 doses in a row, ask your doctor for advice on restarting treatment.

If you stop taking Qsiva

Do not change your Qsiva dose or stop treatment without your doctor's approval. Abrupt stop of treatment increases the risk of seizures. A gradually decrease is recommended if you are taking Qsiva at the highest dose and you need to discontinue.

Contact your doctor for advice about managing your weight and possible dose changes to other medicines you may be using.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects occur in the following frequencies:

Very common (may affect more than 1 in 10 people)

- dry mouth
- constipation
- abnormal sensation such as tingling, prickling, burning or numbness

Common (may affect up to 1 in 10 people)

- lack of appetite, taste disturbance
- sleeping difficulties, depression, anxiety, irritability
- headache
- dizziness, disturbed concentration, tiredness, reduced memory
- reduced sense of touch or sensation
- blurred vision, dry eye
- feeling of increased heartbeat
- nausea, diarrhoea, abdominal pain, indigestion
- hair loss
- thirst, feeling nervous

Uncommon (may affect up to 1 in 100 people)

- urinary tract infection
- lack of red blood cells
- low blood potassium level, low blood sugar level
- tissue swelling caused by excess fluid, dehydration
- increased appetite
- nervousness
- decreased or increased libido
- altered mood, emotional disorder
- excitement, restlessness
- confused state, affected lability, disinterest
- sleep disorder, including abnormal dreams, nightmares
- crying, stress, anger
- panic attack, paranoia
- partial or total memory loss
- sleepiness, lethargy
- uncontrollable shaking
- cognitive disorder, speech disorders
- reduced taste sensation
- migraine
- hyperactivity
- nerve disorder, other than of the brain and spinal cord
- fainting fit
- disorder causing a strong urge to move one's legs
- abnormal coordination
- smell disturbance
- eye pain, eyelid spasm
- unpleasant eye sensitivity to light
- perception flashes of light in the field of vision
- double vision, eye itching
- ringing in the ears
- increased heartbeat
- flushing
- low or high blood pressure
- cough, nosebleed
- breathing difficulties

- pain in the throat and voice box
- blocked sinuses or nose, post-nasal drip
- wind, eructation
- reflux of stomach juices in the oesophagus, vomiting
- itching, nettle-rash, rash, skin reddening, dry skin
- increased sweating, acne, abnormal skin odour
- abnormal hair texture
- pain in arms and legs, muscle pain, back pain, joint pain
- muscle spasms, muscle weakness, muscle twitching
- kidney stones
- frequent urge to urinate without increased urine output, urinary hesitation
- increased nightly urination
- erectile dysfunction
- menstruation disorders
- weakness, abnormal feelings
- swelling of arms and/or legs due to accumulation of fluid
- increased energy, chest pain, feeling cold or hot
- decreased blood levels: bicarbonate, potassium
- abnormal liver function test
- decreased elimination of creatinine, the muscle tissue breakdown product, through kidneys

Rare (may affect up to 1 in 1,000 people)

- infection of breathing organs
- inflammation of the sinuses, flu, inflammation of the bronchial tubes
- Candida yeast fungal infection
- ear infection
- excessive acid in the body due to a metabolic disorder, gout
- suicidal ideation, aggression
- inability to experience pleasure, including having reduced motivation
- bereavement reaction
- grinding of teeth, dislike of food
- hallucination, disorientation
- stuttering
- pins and needles
- increased flow of tears
- increased eye pressure, bleeding in the conjunctiva
- deafness, ear pain
- a heart rhythm disorder which causes very rapid activity in the upper heart chambers, irregular heartbeats
- deep vein thrombosis
- dry throat, runny nose
- bad breath, painful gums, tongue inflammation, burning tongue
- piles, infrequent bowel movement
- gallstones or diseases caused by gallstones
- inflammation of the gallbladder
- breaking of the nails
- muscle tightness
- abnormal urine odour
- gait disturbance
- fall
- increased creatinine blood levels
- increased blood glucose level

Not known (frequency cannot be estimated from the available data)

- inflammation of the stomach and bowel lining through a virus
- hypersensitivity
- excessively talkative, suicide attempt
- seizure
- pain in one or more nerves
- temporary blindness, dilated pupils, clouding of the eye lens
- certain eye disease with degeneration of the centre of the inner eye lining, which can result in loss of central vision
- reduced hearing, accumulation of fluid in the middle ear
- heart weakness
- nasal polyps, acute lung failure
- difficulty in swallowing, discomfort in the mouth, retching
- serious allergic reaction which causes swelling of the face or throat
- acute kidney injury
- sensation of foreign body
- decreased blood glucose level
- increased blood levels: glycosylated haemoglobin, thyroid stimulating hormone, specific blood fat called triglycerides
- inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Qsiva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30 °C. Keep the bottle tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Qsiva contains

The active substances are phentermine and topiramate.

Qsiva 3.75 mg/23 mg hard modified-release capsules

Each hard modified-release capsules contains 3.75 mg of phentermine (as hydrochloride) and 23 mg of topiramate.

The other ingredients are sucrose, maize starch, hypromellose, microcrystalline cellulose, methylcellulose, ethylcellulose, povidone, talc, gelatin, titanium dioxide (E171), Brilliant Blue FCF

(E133), erythrosine (E127), white printing ink (titanium dioxide (E171), shellac, propylene glycol, simeticone).

Qsiva 7.5 mg/46 mg hard modified-release capsules

Each hard modified-release capsules contains 7.5 mg of phentermine (as hydrochloride) and 46 mg of topiramate.

The other ingredients are sucrose, maize starch, hypromellose, microcrystalline cellulose, methylcellulose, ethylcellulose, povidone, talc, gelatin, titanium dioxide (E171), Brilliant Blue FCF (E133), erythrosine (E127), tartazine (E102), Sunset Yellow (E110), black printing ink (iron oxide black (E172), shellac, propylene glycol), white printing ink (titanium dioxide (E171), shellac, propylene glycol, simeticone).

Qsiva 11.25 mg/69 mg hard modified-release capsules

Each hard modified-release capsules contains 11.25 mg of phentermine (as hydrochloride) and 69 mg of topiramate.

The other ingredients are sucrose, maize starch, hypromellose, microcrystalline cellulose, methylcellulose, ethylcellulose, povidone, talc, gelatin, titanium dioxide (E171), tartazine (E102), Sunset Yellow (E110), black printing ink (iron oxide black (E172), shellac, propylene glycol).

Qsiva 15 mg/92 mg hard modified-release capsules

Each hard modified-release capsules contains 15 mg of phentermine (as hydrochloride) and 92 mg of topiramate.

The other ingredients are sucrose, maize starch, hypromellose, microcrystalline cellulose, methylcellulose, ethylcellulose, povidone, talc, gelatin, titanium dioxide (E171), tartazine (E102), Sunset Yellow (E110), black printing ink (iron oxide black (E172), shellac, propylene glycol).

What Qsiva looks like and contents of the pack

Qsiva is a hard modified-release capsules with 2.31 cm length and 0.73 to 0.76 cm diameter.

Qsiva 3.75 mg/23 mg hard modified-release capsules

Qsiva 3.75 mg/23 mg hard modified-release capsules have a purple cap imprinted with VIVUS and a purple body imprinted with 3.75/23.

Qsiva 7.5 mg/46 mg hard modified-release capsules

Qsiva 7.5 mg/46 mg hard modified-release capsules have a purple cap imprinted with VIVUS and a yellow body imprinted with 7.5/46.

Qsiva 11.25 mg/69 mg hard modified-release capsules

Qsiva 11.25 mg/69 mg hard modified-release capsules have a yellow cap imprinted with VIVUS and a yellow body imprinted with 11.25/69.

Qsiva 15 mg/92 mg hard modified-release capsules

Qsiva 15 mg/92 mg hard modified-release capsules have a yellow cap imprinted with VIVUS and a white body imprinted with 15/92.

Qsiva hard modified-release capsules are packaged in a plastic bottle containing a silica gel desiccant and 14 or 30 hard modified-release capsules. The bottle is closed with a tamper-evident, child-resistant white plastic screw-cap.

Do not swallow the desiccant.

Marketing Authorisation Holder

VIVUS BV
Strawinskylaan 4117
1077 ZX Amsterdam
The Netherlands

Manufacturer

Catalent Germany Schorndorf GmbH
Steinbeisstrasse 1-2
73614 Schorndorf
Germany

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>

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