

- Low blood pressure, low blood pressure upon standing (consequently, some people taking Topiramate may feel faint, dizzy, or may pass out when they stand up or sit up suddenly)
- Flushing, feeling warm
- Pancreatitis (inflammation of the pancreas)
- Excessive passing of gas or wind, heartburn, abdominal fullness or bloating
- Bleeding gums, increased saliva, drooling, breath odour
- Excessive intake of fluids, thirst
- Skin discolouration
- Muscle stiffness, pain in side
- Blood in urine, incontinence (lack of control) of urine, urgent desire to urinate, flank or kidney pain
- Difficulty getting or keeping an erection, sexual dysfunction
- Flu-like symptoms
- Cold fingers and toes
- Feeling drunk
- Learning disability.

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

- Abnormally elevated mood
- Loss of consciousness
- Blindness in one eye, temporary blindness, night blindness
- Lazy eye
- Swelling in and around the eyes
- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold
- Inflammation of the liver, liver failure
- Abnormal skin odour
- Discomfort in your arms or legs
- Kidney disorder.

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

- Maculopathy is a disease of the macula, the small spot in the retina where vision is keenest. You should call your doctor if you notice a change or decrease in your vision.

Children

The side effects in children are generally similar to those seen in adults, but the following side effects may be more common in children than adults:

- Problems with concentration
- Increased acid level in the blood
- Having thoughts of serious self-harm
- Tiredness
- Decreased or increased appetite
- Aggression, abnormal behaviour
- Difficulty falling or staying asleep
- Feeling of unsteadiness when walking
- Not feeling well
- Decrease in potassium level in the blood
- Showing and/or feeling no emotion
- Watery eyes
- Slow or irregular heartbeat.

Other side effects that may occur in children are:

- **Common** (may affect up to 1 in 10 people):
- Sensation of spinning (vertigo)
- Vomiting
- Fever.

Uncommon (may affect up to 1 in 100 people):

- Increase in eosinophils (a type of white blood cell) in the blood
- Hyperactivity
- Feeling warm
- Learning disability.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TOPIRAMATE CAPSULES

Keep out of the sight and reach of children.

Store in the original container. Keep the container tightly closed in order to protect from moisture.

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

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Topiramate Capsules contain:

The active substance is topiramate (each capsule contains 15mg or 25mg of topiramate). The other ingredients are sugar spheres (which contain sucrose, maize starch), povidone, aniseed flavour, saccharin sodium (E954), magnesium stearate, gelatin, titanium dioxide (E171) and Opadry-II-85F18378 White (which contains polyvinyl alcohol-part hydrolysed, macrogol, talc and titanium dioxide).

The black printing ink contains shellac, ethanol, isopropanol, butanol, propylene glycol, purified water, strong ammonia solution, potassium hydroxide and black iron oxide (E172).

What Topiramate Capsules look like and contents of the pack:

Your medicine is in the form of hard gelatin capsules.

The 15mg capsules are white with '15' printed in black on the body and '>' over 'Ti' on the cap. The 25mg capsules are white with '25' printed in black on the body and '>' over 'Ti' on the cap.

Topiramate Capsules are available in HDPE bottles containing 14, 20, 28, 56 and 60 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Accord, Barnstaple, EX32 8NS, UK

Manufacturer:

Actavis UK Limited, Whiddon Valley, Barnstaple, North Devon, EX32 8NS, UK

This leaflet was revised in October 2019.

Package leaflet: Information for the user

Topiramate Accord 15mg and 25mg Capsules, hard (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 Topiramate Capsules are and what they are used for
2. What you need to know before you take Topiramate Capsules
3. How to take Topiramate Capsules
4. Possible side effects
5. How to store Topiramate Capsules
6. Contents of the pack and other information

1. WHAT TOPIRAMATE CAPSULES ARE AND WHAT THEY ARE USED FOR

Topiramate Capsules belong to a group of medicines called 'antiepileptic medicines.'

They are used:

- alone to treat seizures in adults and children over age 6
- with other medicines to treat seizures in adults and children aged 2 years and above
- to prevent migraine headaches in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TOPIRAMATE CAPSULES

Do not take Topiramate Capsules:

- if you are allergic to topiramate or any of the other ingredients of this medicine (listed in section 6).
- for migraine prevention; if you are pregnant or if you are a woman of childbearing potential unless you are using effective contraception (see section 'pregnancy and breast-feeding' for further information). You should talk to your doctor about the best kind of contraception to use while you are taking Topiramate Capsules.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Topiramate Capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Topiramate Capsules if you:

- have kidney problems, especially kidney stones, or are getting kidney dialysis
- have a history of blood and body fluid abnormality (metabolic acidosis)
- have liver problems
- have eye problems, especially glaucoma
- have a growth problem
- are on a high fat diet (ketogenic diet)
- are taking Topiramate Capsules to treat epilepsy and you are pregnant or a woman of childbearing potential (see section 'pregnancy and breast-feeding' for further information).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Topiramate Capsules.

It is important that you do not stop taking your medicine without first consulting your doctor.

You should also talk to your doctor before taking any medicine containing topiramate that is given to you as an alternative to Topiramate Capsules.

You may lose weight if you use Topiramate Capsules so your weight should be checked regularly when using Topiramate Capsules. If you are losing too much weight or a child using Topiramate Capsules is not gaining enough weight, you should consult your doctor.

A small number of people being treated with anti-epileptic medicines such as Topiramate Capsules have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Topiramate Capsules may in rare cases cause high levels of ammonia in the blood (seen in blood tests) which can lead to a change in brain function, especially if you are also taking a medicine called valproic acid or sodium valproate. Since this may be a severe condition, tell your doctor immediately if the following symptoms occur (see also section 4 'Possible side effects'):

- difficulty thinking, remembering information, or solving problems
- being less alert or aware
- feeling very sleepy with low energy

At higher doses of Topiramate Capsules, the risk of developing these symptoms may increase.

Other medicines and Topiramate Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Topiramate and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or topiramate will have to be adjusted.

Especially, tell your doctor or pharmacist if you are taking:

- Other medicines that impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines such as muscle relaxants and sedatives).
- Birth control pills. Topiramate Capsules may make your birth control pills less effective. You should talk to your doctor about the best kind of contraception to use while you are taking Topiramate Capsules.

Tell your doctor if your menstrual bleeding changes while you are taking birth control pills and Topiramate Capsules.

Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine.

Other medicines you should discuss with your doctor or pharmacist include other antiepileptic medicines, risperidone, lithium, hydrochlorothiazide, metformin, pioglitazone, glibenclamide, amitriptyline, propranolol, diltiazem, venlafaxine, flunarizine, St. John's wort (*Hypericum perforatum*) (a herbal preparation used to treat depression) and warfarin used to thin the blood.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Topiramate Capsules.

Topiramate Capsules with food, drink and alcohol

You can take topiramate with or without food. Drink plenty of fluids during the day to prevent kidney stones while taking Topiramate Capsules. You should avoid drinking alcohol when taking topiramate.

Pregnancy and breast-feeding

Migraine prevention

Topiramate Capsules can harm an unborn baby. You must not use Topiramate Capsules if you are pregnant. You must not use Topiramate Capsules for migraine prevention if you are a woman of childbearing potential unless you are using effective contraception. Talk to your doctor about the best kind of contraception and whether Topiramate Capsules are suitable for you. Before the start of treatment with Topiramate Capsules a pregnancy test should be performed.

Treatment of epilepsy

If you are a woman of childbearing potential you should talk to your doctor about other possible treatments instead of Topiramate Capsules. If the decision is made to use Topiramate Capsules, you should use effective contraception.

Talk to your doctor about the best kind of contraception to use while you are taking Topiramate Capsules. Before the start of treatment with Topiramate Capsules a pregnancy test should be performed.

Talk to your doctor if you wish to become pregnant

As with other antiepileptic medicines, there is a risk of harm to the unborn child if Topiramate Capsules are used during pregnancy. Make sure you are very clear about the risks and the benefits of using Topiramate Capsules for epilepsy during pregnancy.

- If you take Topiramate Capsules during pregnancy, your baby has a higher risk for birth defects, particularly cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth). 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 Topiramate Capsules during pregnancy, your baby may be smaller than expected at birth. Talk to your doctor if you have questions about this risk during pregnancy.
- There may be other medicines to treat your condition that have a lower risk of birth defects.
- Tell your doctor straight away if you become pregnant while taking Topiramate Capsules. You and your doctor should decide if you will continue to take Topiramate Capsules while you are pregnant.

Breast-feeding

The active substance in Topiramate Capsules (topiramate) passes into human milk. Effects have been seen in breast-fed babies of treated mothers, including diarrhoea, feeling sleepy, feeling irritable, and poor weight gain.

Therefore, your doctor will discuss with you whether you abstain from breast-feeding or whether to abstain from treatment with Topiramate Capsules. Your doctor will take into account the importance of the medicine to the mother and the risk for the baby. Mothers who breast-feed while taking topiramate must tell the doctor as soon as possible if the baby experiences anything unusual.

Driving and using machines

Dizziness, tiredness, and vision problems may occur during treatment with topiramate. Do not drive or use any tools or machines without talking to your doctor first.

Topiramate Capsules contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23mg) per hard capsule, that is to say essentially 'sodium-free'.

3. HOW TO TAKE TOPIRAMATE CAPSULES

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

- Your doctor will usually start you on a low dose of topiramate and slowly increase your dose until the best dose is found for you.
- Topiramate Capsules may be swallowed whole or may be opened and sprinkled on a teaspoon of soft food of any type. Examples are apple sauce, custard, ice cream, porridge, pudding or yoghurt. Drink fluids right after to make sure all of the food and medicine mixture is swallowed.
- Hold the hard capsule upright so that the wording is the correct way up.
- Carefully twist off the top part (cap) of the capsule. You may find it best to do this over the small portion of food onto which you will be pouring the sprinkles.
- Sprinkle all of the capsule's contents onto a spoonful of soft food, taking care to see that the entire prescribed dosage is sprinkled onto the food.
- Be sure to swallow the entire spoonful of the sprinkle/food mixture immediately. Avoid chewing.
- Drink fluids immediately in order to make sure all of the mixture is swallowed.
- Never store any medicine and food mixture for use at a later time.
- Topiramate Capsules can be taken before, during, or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking topiramate.

If you take more Topiramate Capsules than you should

- See a doctor right away. Take the medicine pack with you.
- You may feel sleepy, tired, or less alert; lack coordination; have difficulty speaking or concentrating; have double or blurred vision; feel dizzy due to low blood pressure; feel depressed or agitated; or have abdominal pain, or seizures (fits).

Overdose can happen if you are taking other medicines together with Topiramate Capsules.

If you forget to take Topiramate Capsules

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Topiramate Capsules

Do not stop taking Topiramate Capsules unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop Topiramate Capsules, your dose may be decreased gradually over a few days.

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.

Tell your doctor, or seek medical attention immediately if you have the following side effects:

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

- Depression (new or worse).

Common (may affect up to 1 in 10 people):

- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)
- Seizures (fits)
- Anxiety, irritability, changes in mood, confusion, disorientation
- Problems with concentration, slowness of thinking, loss of memory, problems with memory (new onset, sudden change or increased severity)
- Kidney stone, frequent or painful urination.

Uncommon (may affect up to 1 in 100 people):

- Increased acid level in the blood (may cause troubled breathing including shortness of breath, loss of appetite, nausea, vomiting, excessive tiredness, and fast or uneven heart beats)
- Decreased or loss of sweating (particularly in young children who are exposed to high temperatures)
- Having thoughts of serious self-harm, trying to cause serious self-harm
- Loss of part of the field of vision.

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

- Stevens Johnson syndrome, a potentially life-threatening condition that may present with sores in multiple mucosal sites (such as the mouth, nose, and eyes), a skin rash, and blistering
- Glaucoma – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision
- Difficulty thinking, remembering information, or solving problems, being less alert or aware, feeling very sleepy with low energy – these symptoms may be a sign of a high level of ammonia in the blood (hyperammonemia), which can lead to a change in brain function (hyperammonemic encephalopathy).

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

- Toxic epidermal necrosis, a life-threatening condition related to, yet more severe than, Stevens-Johnson syndrome, characterized by widespread blistering and sloughing of the outer layers of the skin (see rare side effects)
- Inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred vision.

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

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

- Stuffy, runny nose or sore throat
- Tingling, pain and/or numbness of various body parts
- Sleepiness, tiredness
- Dizziness
- Nausea, diarrhoea
- Weight loss.

Common (may affect up to 1 in 10 people):

- Anaemia (low blood count)
- Loss of appetite, decreased appetite
- Aggression, agitation, anger, abnormal behaviour
- Difficulty falling or staying asleep
- Problems with speech or speech disorder, slurred speech
- Clumsiness or lack of coordination, feeling of unsteadiness when walking
- Decreased ability to complete routine tasks
- Decreased, loss of, or no sense of taste
- Involuntary trembling or shaking; rapid, uncontrollable movements of the eyes
- Visual disturbance, such as double vision, blurred vision, decreased vision, difficulty focusing
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Shortness of breath
- Cough
- Nose bleeds
- Fever, not feeling well, weakness
- Vomiting, constipation, abdominal pain or discomfort, indigestion, stomach or intestinal infection
- Dry mouth
- Hair loss
- Itching
- Joint pain or swelling, muscle spasms or twitching, muscle aches or weakness, chest pain
- Weight gain.

Uncommon (may affect up to 1 in 100 people):

- Decrease in platelets (blood cells that help stop bleeding), decrease in white blood cells that help to protect you against infection, decrease in potassium level in the blood
- Increase in liver enzymes, increase in eosinophils (a type of white blood cell) in the blood
- Swollen glands in the neck, armpit, or groin
- Increased appetite
- Elevated mood
- Hearing, seeing, or feeling things that are not there, severe mental disorder (psychosis)
- Showing and/or feeling no emotion, unusual suspiciousness, panic attack
- Problems with reading, speech disorder, problems with handwriting
- Restlessness, hyperactivity
- Slowed thinking, decreased wakefulness or alertness
- Reduced or slow body movements, involuntary abnormal or repetitive muscle movements
- Fainting
- Abnormal sense of touch; impaired sense of touch
- Impaired, distorted, or no sense of smell
- Unusual feeling or sensation that may precede a migraine or a certain type of seizure
- Dry eye, sensitivity of the eyes to light, eyelid twitching, watery eyes
- Decreased or loss of hearing, loss of hearing in one ear
- Slow or irregular heartbeat, feeling your heart beating in your chest