

PACKAGE LEAFLET: Information for the patient

TOPIRAMAT

Film-coated tablets – 25 mg

(Topiramate)

Read all of this leaflet carefully before you start taking this medicine.

- 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.

In this leaflet:

1. What Topiramate is and what it is used for
2. Before you take Topiramate
3. How to take Topiramate
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1. WHAT TOPIRAMAT IS AND WHAT IT IS USED FOR

Topiramate belongs to a group of medicines called “anti-epileptic medicines”. It is used:

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

2. BEFORE YOU TAKE TOPIRAMAT

Do not take Topiramate:

- if you are allergic to topiramate or any of the excipients 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 breastfeeding' for further information). You should talk to your doctor about the best kind of contraception to use while you are taking Topiramate.

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

Take special care with Topiramate

Talk to your doctor or pharmacist before taking Topiramate 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 to treat epilepsy and you are pregnant or a woman of childbearing potential (see section 'Pregnancy and breastfeeding' for further information).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Topiramate. 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. You may lose weight if you use Topiramate so your weight should be checked regularly when using this medicine. If you are losing too much weight or a child using this medicine is not gaining enough weight, you should consult your doctor.

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

Topiramate 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, the risk of developing these symptoms may increase.

Other medicines and Topiramate

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

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 anti-epileptic medicines, risperidone, lithium, hydrochlorothiazide, metformin,
pioglitazone, glibenclamide, amitriptyline, propranolol, diltiazem, venlafaxine, flunarizine,
digoxin, moclobemide, imipramine, proguanil, haloperidol, omeprazole, St. John's wort
(*Hypericum perforatum* that is a herbal preparation used to treat depression), warfarin (used to
thin the blood).

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

Topiramate with food and drinks

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

Pregnancy and breastfeeding

Migraine prevention

Topiramate can harm an unborn baby. You must not use Topiramate if you are pregnant. You must
not use Topiramate 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 is suitable for you. Before the start of treatment with Topiramate, 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. If the decision is made to use Topiramate, you should use
effective contraception. Talk to your doctor about the best kind of contraception to use while
you are taking Topiramate. Before the start of treatment with Topiramate, a pregnancy test should
be performed.

Talk to your doctor if you wish to become pregnant. As with other anti - epileptic medicines, there is a risk of harm to the unborn child if Topiramate is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Topiramate for epilepsy during pregnancy.

- If you take Topiramate 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 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. You and your doctor should decide if you will continue to take Topiramate while you are pregnant.

Breastfeeding

Topiramate passes into human milk. Effects have been seen in breastfed babies of treated mothers, including diarrhea, 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. 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 contains lactose

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

3. HOW TO TAKE TOPIRAMATE

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 tablets are to be swallowed whole. Avoid chewing the tablets as they may leave a bitter taste. Topiramate 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 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 and stomach pain, or seizures (fits), abnormal body movements, changes in thinking and alertness, loss of consciousness.

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

If you forget to take Topiramate

- 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

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

If you have any further questions on the use of this medicinal product, 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:

Common (may affect up to 1 in 10 people)

- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives).

Uncommon (may affect up to 1 in 100 people)

- Having thoughts of serious self-harm, trying to cause serious self-harm.

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

- Glaucoma – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision
- 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.

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.
- Toxic epidermal necrolysis, a life-threatening condition related to, yet more severe than, Stevens-Johnson syndrome, characterised 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)

- Depression (new or worse)
- 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)

- 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
- Anaemia (low blood count)
- Loss of appetite, decreased appetite, weight gain
- 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, dry mouth
- 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
- Hair loss, itching
- Joint pain or swelling, muscle spasms or twitching, muscle aches or weakness, chest pain.

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)
- Loss of part of the field of vision
- 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, 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
- Disturbances in sexual sensations.

Children and adolescents

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TOPIRAMAT

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the package.

Do not store above 25°C.

6. OTHER INFORMATION

What Topiramat 25 mg film-coated tablets contain

The **active substance** is topiramate

Each film-coated tablet contains 25 mg topiramate.

The **excipients** are: lactose monohydrate and corn starch, microcrystalline cellulose, talc, magnesium stearate, crospovidone, polyvinyl alcohol, titanium dioxide, macrogol.

Content of the pack

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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This leaflet was last revised in October 2023.