

TOPAGAN 25 mg film-coated tablets
TOPAGAN 50 mg film-coated tablets
TOPAGAN 100 mg film-coated tablets
TOPAGAN 200 mg film-coated tablets

Topiramate

Read this leaflet carefully before using the medicine because it contains important information for you.

- Keep this leaflet, as you may need to read it again.
- If you have any question, consult your doctor or pharmacist.
- This medicine has been prescribed to you only and it should not be given to other people, even if the symptoms are the same as yours, since it can harm them.
- If any of the adverse effects you suffer are severe or if you notice any adverse effects not mentioned in this leaflet, inform your doctor or pharmacist.

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1. What TOPAGAN film-coated tablets is and what it is used for

TOPAGAN belongs to a group of medicines called antiepileptics. It is indicated:

- For single-drug therapy in adults and children above 6 years of age.
- For concomitant treatment with other medicines in adults and children from 2 years of age.
- As preventive treatment for migraine in adults.

2. What you need to know before taking TOPAGAN film-coated tablets

• Do not take TOPAGAN:

- If you are allergic (hypersensitive) to topiramate or to any of the other ingredients of this medicine (included 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 TOPAGAN.

If you are unsure if any of the above applies to you, consult your doctor or pharmacist before taking TOPAGAN.

• Take special care with TOPAGAN:

Before starting treatment with TOPAGAN, consult your doctor or pharmacist:

- If you have any kidney problem, especially kidney stones, or you are being dialyzed.
- If you have a history of abnormalities in blood or body fluids (metabolic acidosis)
- If you have any liver disease.
- If you have any problem in the eyes, especially glaucoma.
- If you have growing problems.
- If your diet is high in fat (cetogenic diet).
- Are taking TOPAGAN to treat epilepsy and you are pregnant or a woman of childbearing potential (see section 'Pregnancy and breastfeeding' for further information).

If you are unsure if any of the above applies to you, consult your doctor or pharmacist before using TOPAGAN.

It is important not to stop taking your medication without first consulting your doctor.

You should consult your doctor before taking any other medicines containing topiramate given as an alternative to TOPAGAN.

You can lose weight if you take TOPAGAN so your weight should be monitored regularly while taking this medicine. If you lose too much weight or a child who is taking this medicine does not gain enough weight, you should consult your doctor.

A small number of people being treated with antiepileptic drugs such as TOPAGAN have had thoughts of harming or killing themselves. If you ever have these thoughts, immediately contact your doctor.

Interaction of TOPAGAN with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken or may have to take any other medicines, TOPAGAN and certain medications can affect each other. Sometimes the dosage of TOPAGAN or any other medicines must be adjusted.

Specially inform your doctor or pharmacist if you are taking:

- Other medicines that impair or tend to lower your thoughts, concentration, or muscle coordination (eg. depressants of central nervous system such as sedatives and muscle relaxants).
- Contraceptives. TOPAGAN may decrease the effectiveness of the contraceptive pill you are taking.

Tell your doctor if your menstrual bleeding changes while taking contraceptive pills and TOPAGAN. You should talk to your doctor about the best kind of contraception to use while you are taking TOPAGAN.

Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before using TOPAGAN.

Other drugs for which you should consult your doctor or pharmacist include other antiepileptic drugs, risperidone, lithium, hydrochlorothiazide, metformin, pioglitazone, glyburide, amitriptyline, propranolol, diltiazem, venlafaxine, flunarizine.

If you are unsure if any of the above applies to you, consult your doctor or pharmacist before taking TOPAGAN.

• TOPAGAN with food, drink and alcohol:

TOPAGAN can be taken with or without food. You should drink plenty of fluids during the day to prevent the formation of kidney stones while taking TOPAGAN. You should avoid drinking alcohol while taking TOPAGAN.

• Pregnancy, breast-feeding and fertility:

Your doctor will decide if you should take TOPAGAN. Talk to your doctor if you wish to become pregnant. Like any other antiepileptic drug, there is a risk of damage to the fetus if TOPAGAN is used during pregnancy. Make sure you have very clear the risks and benefits of using TOPAGAN for epilepsy during pregnancy.

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

Migraine prevention:

TOPAGAN can harm an unborn baby. You must not use TOPAGAN if you are pregnant. You must not use TOPAGAN 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 TOPAGAN is suitable for you. Before the start of treatment with TOPAGAN a pregnancy test should be performed.

Breast-feeding:

The active substance in TOPAGAN (topiramate) passes into breast 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 breastfeeding or whether to abstain from treatment with TOPAGAN. 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 TOPAGAN must tell the doctor as soon as possible if the baby experiences anything unusual. Breast-feeding mothers who are taking TOPAGAN should inform their doctor as soon as possible if the baby has something unusual.

Treatment of epilepsy:

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

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

Consult your doctor or pharmacist before taking any medication.

Talk to your doctor if you wish to become pregnant.

• Driving and using machines:

There may be dizziness, fatigue and visual disturbances during treatment with TOPAGAN. Do not drive or operate any tools or machines without talking to your doctor.

Important information about some of the components of TOPAGAN

This medicine contains lactose. If your doctor has informed you that you suffer intolerance to some sugars, ask him/her before using this medicine.

3. How to take TOPAGAN film-coated tablets

Always take TOPAGAN exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

- Take TOPAGAN exactly as prescribed. Your doctor will usually start with a low dose of topiramate and slowly increase your dosage to find the best for you.
- TOPAGAN tablets are swallowed whole. Avoid chewing the tablets as they may leave a bitter taste.
- You can take TOPAGAN before, during or after a meal. Drink plenty of fluids during the day to avoid the formation of kidney stones while taking TOPAGAN.

• If you take more TOPAGAN than you should:

- Ask immediately your doctor or pharmacist. Take the medicine with you.
- You may feel sleepy or tired, or have abnormal body movements, trouble standing and walking, feel dizzy due to a drop in blood pressure, or have abnormal heartbeat or seizures.

Overdose can occur if you are taking other medications along with TOPAGAN.

• If you forgot to take TOPAGAN

- If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and continue as usual. Consult your doctor if you miss two or more doses.
- Do not take a double dose (two doses at the same time) to make up the missed dose.

• If you stop taking TOPAGAN

Do not stop treatment unless your doctor tells you to. Symptoms of your disease may reappear. If your doctor decides you should stop taking this medication, decrease your dose gradually over several days.

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



4. Possible side effects

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

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

Very common side effects include:

- Weight loss
- Tingling in the arms and legs
- Drowsiness or sleepiness
- Dizziness
- Diarrhoea
- Nausea
- Stuffy, runny nose and sore throat
- Tiredness
- Depression

Common side effects include:

- Changes in mood or behaviour, including anger, nervousness, sadness
- Weight gain
- Decrease or loss of appetite
- Reduced number of red blood cells
- Changes in thinking and alertness, including confusion, problems with concentration, memory or slowness in thinking
- Slurred speech
- Clumsiness or problems with walking
- Involuntary shaking in the arms, hands or legs
- Reduced sense of touch or sensation
- Involuntary movement of the eyes
- Distorted sense of taste
- Visual disturbance, blurred vision, double vision
- Ringing sound in the ears
- Ear pain
- Shortness of breath
- Nose bleeds
- Vomiting
- Constipation
- Stomach pain
- Indigestion
- Dry mouth
- Tingling or numbness of the mouth
- Kidney stones
- Frequent urination
- Painful urination
- Hair loss
- Skin rash and/or itchy skin
- Joint pain
- Muscle spasms, muscle twitching or muscle weakness
- Chest pain
- Fever
- Loss of strength
- General feeling of feeling unwell
- Allergic reaction

Uncommon side effects include:

- Crystals in the urine
- Abnormal blood counts, including reduced white blood cell count or platelet count, or increased eosinophils
- Irregular heartbeat or slowness of the heartbeat
- Swollen glands in the neck armpit or groin
- Increase in seizures
- Problems with verbal communication
- Drooling
- Restlessness or increased mental and physical activity
- Loss of consciousness
- Fainting
- Slow or diminished movements
- Disturbed or poor quality sleep
- Impaired or distorted sense of smell
- Problems with handwriting
- Feeling of movement under the skin
- Eye problems including dry eyes, light sensitivity, involuntary twitching, tearing and decreased vision
- Decreased or loss of hearing
- Hoarseness of the voice
- Inflammation of the pancreas
- Gas
- Heartburn
- Loss of sensitivity to touch in the mouth
- Bleeding gums
- Fullness or bloating
- Painful or burning sensations in the mouth
- Breath odour
- Leakage of urine and/or stools
- Urgent desire to urinate
- Pain in the kidney area and/or bladder caused by kidney stones
- Decrease or loss of sweating
- Skin discolouration
- Localized swelling in the skin
- Swelling of the face
- Swelling of the joints
- Musculoskeletal stiffness
- Increased acid levels in the blood
- Low potassium levels in the blood
- Increased appetite

- Increased thirst and drinking abnormally large amounts of fluid
- Low blood pressure or decrease in blood pressure that occurs when you stand up
- Hot flushing
- Flu like illness
- Cold extremities (e.g., hands and face)
- Problems with learning
- Disturbances in sexual function (erectile dysfunction, loss of libido)
- Hallucinations
- Decreased verbal communication

Rare side effects include:

- Excessive skin sensitivity
- Impaired sense of smell
- Glaucoma which is a blockage of fluid in the eye causing increased pressure in the eye, pain and decreased vision
- Renal tubular acidosis
- Severe skin reaction, including Stevens-Johnson syndrome, a life threatening skin condition in which the upper layer of the skin separates from the lower, and erythema multiforme, a condition of raised red spots that can blister
- Odour
- Swelling in the tissues around the eye
- Raynaud's syndrome. A disorder affecting the blood vessels, in the fingers, toes, ears and causing pain and cold sensitivity
- Tissue calcification (calcinosis)

Side effects of unknown frequency

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

Swelling of the conjunctiva of the eye

Toxic epidermal necrolysis which is a more severe form of Stevens-Johnson syndrome (see uncommon side effects)

If you get side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store TOPAGAN

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date shown on the packaging after Exp. Expired date is the last day of the month indicated.

Do not store above 25°C. Keep the blister perfectly closed to protect it from humidity.

Medicinal products should not be poured down the drain or thrown into the rubbish. Ask your pharmacist how to dispose of medicinal products you do not need. This will help protect the environment.

6. Further information

Composition of TOPAGAN

The active ingredient is topiramate.

TOPAGAN 25 mg film-coated tablets

Each film-coated tablet of TOPAGAN 25 mg film-coated tablets contains 25 mg of topiramate.

The other ingredients (excipients) of TOPAGAN are listed below: Core: lactose anhydrous, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate and colloidal silica.

Coating: Hypromellose, titanium dioxide (E-171) and macrogol 6000.

TOPAGAN 50 mg film-coated tablets

Each film-coated tablet of TOPAGAN 50 mg film-coated tablets contains 50 mg of topiramate.

The other ingredients (excipients) of TOPAGAN are listed below: Core: lactose anhydrous, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate and colloidal silica.

Coating: Hypromellose, titanium dioxide (E-171) and macrogol 6000. Pigment: Yellow iron oxide (E-172).

TOPAGAN 100 mg film-coated tablets

Each film-coated tablet of TOPAGAN 100 mg film-coated tablets contains 100 mg of topiramate.

The other ingredients (excipients) of TOPAGAN are listed below: Core: lactose anhydrous, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate and colloidal silica.

Coating: Hypromellose, titanium dioxide (E-171) and macrogol 6000. Pigment: Yellow iron oxide (E-172).

TOPAGAN 200 mg film-coated tablets

Each film-coated tablet of TOPAGAN 200 mg film-coated tablets contains 200 mg of topiramate.

The other ingredients (excipients) of TOPAGAN are listed below: Core: lactose anhydrous, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate and colloidal silica.

Coating: Hypromellose, titanium dioxide (E-171) and macrogol 6000. Pigment: Iron oxide red (E-172).

Product appearance and contents of the package

TOPAGAN 25 mg film-coated tablets: contains 60 film-coated tablets, white or almost white, round biconvex and marked.

TOPAGAN 50 mg film-coated tablets: contains 60 film-coated tablets, yellow, round biconvex and marked.

TOPAGAN 100 mg film-coated tablets: contains 60 film-coated tablets, yellow, round biconvex and marked.

TOPAGAN 200 mg film-coated tablets: contains 60 film-coated tablets, red to reddish, round, biconvex and marked.

Marketing authorization holder and manufacturer

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