

PACKAGE LEAFLET: INFORMATION FOR THE USER

TIRAMAT

25mg Film-coated tablets

TOPIRAMATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What TIRAMAT is and what it is used for
2. Before you take TIRAMAT
3. How to take TIRAMAT
4. Possible side effects
5. How to store TIRAMAT

1. WHAT TIRAMAT IS AND WHAT IS IT USED FOR

Topiramate belongs to a group of medicines called antiepileptic medicines. It is used

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

2. BEFORE YOU TAKE TIRAMAT

Do not take TIRAMAT tablets and tell your doctor

- if you are **allergic** (hypersensitive) to topiramate or any of the other ingredients of TIRAMAT tablets.
- for migraine prevention **do not take if you are pregnant** or you are able to become pregnant but you are **not using effective contraception** (see 'Pregnancy and breastfeeding' for further information).
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Check with your doctor or pharmacist before taking TIRAMAT tablets if you

- have **kidney problems**, especially kidney stones, or are having **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**.
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Other warnings

- 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 other medicine containing topiramate that is given to you as an alternative to TIRAMAT tablets.
- You may experience significant and continuing **weight loss** while taking TIRAMAT tablets. Therefore your weight should be checked regularly when using this medicine. If you are losing too much weight or if 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 TIRAMAT tablets have had **thoughts of harming or killing themselves**. If at any time you have these thoughts, **contact your doctor at once**.
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Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins and herbal medicines. Topiramate and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or TIRAMAT tablets 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** as Topiramate may make these pills less effective. If your menstrual bleeding changes, you have breakthrough bleeding or spotting, tell your doctor.
- **other antiepileptic** medicines
- risperidone, lithium, amitriptyline, venlafaxine (for depression)
- hydrochlorothiazide, propranolol, diltiazem (for angina and high blood pressure)
- metformin, pioglitazone, glyburide (anti diabetic medicines)
- flunarazine.
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Taking TIRAMAT tablets with food and drink

You can take TIRAMAT tablets with or without food.

To prevent kidney stones whilst being treated with TIRAMAT tablets, drink plenty of fluids during the day.

You should avoid drinking alcohol when taking TIRAMAT tablets.

Pregnancy and breast-feeding

Talk to your doctor before using TIRAMAT tablets if you are pregnant, trying to become pregnant or are breast-feeding. Your doctor will decide if you can take TIRAMAT tablets.

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

You should not take Topiramate for migraine prevention if you are pregnant or are able to become pregnant and are not using effective contraception.

Mothers who breastfeed while taking TIRAMAT tablets must tell the doctor as soon as possible if the baby experiences anything unusual.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Dizziness, tiredness and vision problems may occur whilst taking TIRAMAT tablets. Do not drive or use any tools or machines without talking to your doctor first.

3. HOW TO TAKE TIRAMAT

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

Your doctor will usually start you on a low dose and slowly increase your dose until the best dose is found.

Swallow whole. **Do not chew.** Take with or without food. To prevent kidney stones while taking TIRAMAT tablets, **drink plenty of fluids during the day.**

If you take TIRAMAT tablets only for epilepsy

- Adults – starting dose of 25mg at night. The dose will be slowly increased to a maintenance dose, usually 100-200mg a day in 2 divided doses. Maximum dose of 500mg a day in 2 divided doses.
- Children over 6 years of age – starting dose of 0.5-1mg per kg of body weight at night increasing slowly to a maintenance dose, usually 100mg a day.
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If you take TIRAMAT tablets with another epilepsy medicine

- Adults – starting dose of 25-50mg at night. The dose will be slowly increased to a maintenance dose, usually 200-400mg a day in 2 divided doses.
- Children over 2 years of age – starting dose of 1-3mg per kg of body weight at night increasing slowly to a maintenance dose, usually 5-9mg per kg of body weight a day in 2 divided doses.

Prevention of migraines

- Adults – starting dose of 25mg at night. The dose will be slowly increased to a maintenance dose of 100mg a day in 2 divided doses.
- Children – Not recommended for use in children.
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If you take more TIRAMAT tablets than you should

See a doctor right away. Take the medicine pack with you.

Signs and symptoms of overdose may include; feeling sleepy or tired, abnormal body movements, problems standing and walking, feeling dizzy due to low blood pressure, abnormal heart beats or fits, double vision, changes in thinking and alertness, loss of consciousness, speech problems, changes in mood or behaviour (including anger or depression), stomach pain.

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

If you forget to take TIRAMAT tablets

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 TIRAMAT tablets

Do not stop taking this medicine even if you feel better unless your doctor tells you to as 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Contact your doctor at once if you have the following side effects:

- signs of an **allergic reaction** such as difficulty breathing, swelling of the face, lips, trunk and limbs, hives, skin rash and redness or severe skin reactions such as flushing, blisters and ulcers.

- **severe skin reactions**, 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.
- Toxic epidermal necrolysis which is a more severe form of Stevens-Johnson syndrome.
- 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.
- problems with the eyes including signs of **raised pressure in the eye** (glaucoma) such as blurred or decreased vision, eye pain and redness of the eyes.
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Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Very common (affects more than 1 user in 10):

- weight loss, diarrhoea, feeling sick
- tingling in the arms and legs
- drowsiness or sleepiness, tiredness, dizziness
- stuffy, runny nose and sore throat
- depression

Common (affects 1 to 10 users in 100):

- changes in mood or behaviour including anger, nervousness, sadness
- changes in thinking and alertness including confusion, problems with concentration, memory or slowness in thinking
- weight gain, decrease or loss of appetite
- being sick, constipation, stomach pain, indigestion
- dry mouth, altered sense of taste, tingling or numbness of the mouth
- kidney stones causing sudden pain in the abdomen, frequent or painful urination
- reduced number of red blood cells. You may notice excessive tiredness, paleness of the skin.
- slurred speech, clumsiness or problems with walking, involuntary shaking in the arms, hands or legs
- reduced sense of touch or sensation
- ringing sound in the ears, ear pain
- shortness of breath, nose bleeds
- skin rash and/or itchy skin, hair loss
- joint pain, muscle spasms, muscle twitching or muscle weakness, loss of strength
- chest pain
- fever, general feeling of being unwell

Uncommon (affects 1 to 10 users in 1,000):

- wind, heartburn, fullness or bloating, increased appetite
- increased thirst and drinking abnormally large amounts of fluid
- crystals in the urine, leakage of urine and/or stools, urgent desire to urinate
- changes in the numbers and types of blood cells. You may notice increased bruising, nosebleeds, sore throats, infections, breathlessness on exertion.
- increased acid levels in the blood, low potassium levels in the blood (causing muscle twitching or weaknesses, abnormal heart beat)
- irregular heartbeat or slowness of the heart beat
- swollen glands in the neck armpit or groin
- increase in seizures
- problems with or decreased verbal communication, problems with learning or handwriting
- drooling, decreased or loss of sweating
- restlessness or increased mental and physical activity, hallucinations, loss of consciousness, fainting, disturbed or poor quality sleep
- reduced or altered sense of smell
- feeling of movement under the skin, skin discolouration, pins and needles
- decreased or loss of hearing, hoarseness of the voice

- inflammation of the pancreas, causing severe abdominal pain
- loss of sensitivity to touch in the mouth, painful or burning sensations in the mouth, breath odour, bleeding gums
- swelling of the joints, stiffness, slow or reduced movements
- low blood pressure or drop in blood pressure that occurs when you stand up
- hot flushing, flu like illness, cold extremities (e.g. hands and feet)
- disturbances in sexual function (erectile dysfunction, loss of libido)

Rare (affects 1 to 10 users in 10,000):

- excessive skin sensitivity, odour
- renal tubular acidosis
- raynaud's syndrome. A disorder affecting the blood vessels, in the fingers, toes, ears and causing pain and cold sensitivity
- abdominal build up of calcium salts in the tissues
- increase in liver enzymes seen in tests
- yellowing of the skin or eyes, or tiredness, pain in the abdomen, joints or muscles (hepatitis, hepatic failure)

Unknown (cannot be estimated from the available data):

- cough
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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.

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

5. HOW TO STORE TIRAMAT

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.