

EPIMATE TABLET

Topiramate (50 mg, 100 mg)

What is in this leaflet

1. What is Epimate used for
2. How Epimate works
3. Before you use Epimate
4. How to use Epimate
5. While you are using it
6. Side effects
7. Storage and Disposal of Epimate
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Epimate is used for

Epimate tablet is indicated as adjunctive therapy in adults and children age between 2-16 years seizure with partial onset seizures, or primary generalized tonic-clonic seizures.

Epimate tablet is also indicated as adjunctive therapy in adults and children for the treatment of seizures associated with Lennox-Gastaut syndrome (a type of epilepsy).

How Epimate works

Topiramate belongs to a group of medicines called "antiepileptic medicines."

An epileptic seizure occurs as the result of abnormal electrical signals in the brain. Topiramate prevents fits by stabilising the electrical signals in the brain.

Before you use Epimate

- When you must not use it Do not take Epimate if:

- You are allergic (hypersensitive) to topiramate or any of the other ingredients.

As with other anti-epileptic medicines, there is a risk of harm of the unborn child if Epimate is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Epimate during pregnancy

- If you take Epimate during pregnancy, your baby has higher risk of 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.

- Your child is also at risk for developing autism and other intellectual disabilities.
- There may be other medicines to treat your condition that have lower risk of birth defects.
- Tell your doctor straight away if you become pregnant or planning to get pregnant while taking Epimate. You and your doctor should decide if you will continue to take Epimate while you are pregnant.
- It is important that you do not stop taking your medicine without first consulting your doctor.
- You should talk to your doctor about the best kind of birth control to use while you are taking Epimate. You should use effective contraception. Before the start of treatment with Epimate, a pregnancy test should be performed. Talk to your doctor if you wish to become pregnant.

Pregnancy and lactation

Do not take Epimate if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Epimate if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

You must tell your doctor or pharmacist if you:

Have kidney problems, especially kidney stones, or are getting kidney dialysis.

- Have personality disorder or mental illness.
- Have liver problems.
- Have eye problems, especially glaucoma.
- Have decreased sweating and an elevation in body temperature.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking:

- Other medicines for epilepsy, such as phenytoin or carbamazepine.
- Digoxin (used to treat heart disease).
- Oral contraceptives (the pill).
- Metformin, pioglitazone (used to treat diabetes).
- Acetazolamide (used to treat glaucoma).
- Lithium, risperidone (used to treat bipolar disorder and schizophrenia).
- Hydrochlorothiazide (used to treat swelling or high blood pressure).
- Valproic acid (used to treat certain types of seizures).

How to use Epimate

- How much to use

It is recommended that therapy be initiated at a low dose followed by titration to an effective dose. Tablets should not be broken.

Adult: Treatment starts at a low dose of 25 mg to 50 mg per day nightly for 1 week. The dose is then gradually increased by 25-50 mg/day (to 100 mg/day) and taken in 2 divided doses

Children ≥ 2 years: The recommended total daily dose of Topiramate Tablet as adjunctive therapy is approximately 5-9 mg/kg/day in 2 divided doses. Titration should begin at 25 mg (or less, based on a range of 1-3 mg/kg/day) nightly for the 1st week. The dosage should then be increased at 1 or 2 week intervals by increments of 1-3 mg/kg/day

(administered in 2 divided doses) to achieve optimal clinical response.

- When to use it

At the start of treatment Epimate may be taken once a day, preferably at night. You can take the tablets with or without food. Always swallow the tablets whole with plenty of water.

- How long to use it

Continue taking Epimate for as long as your doctor recommends

- If you forget to use it

It is important to take your Epimate tablet regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to

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make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs and symptoms included:

- Convulsions.
- Drowsiness.
- Speech disturbance.
- Blurred vision.
- Double vision.
- Mental activity impaired.
- Lethargy.
- Body produces too much acid.
- Abnormal coordination.
- Stupor (a state of near- unconsciousness).
- Low blood pressure.
- Abdominal pain.
- Agitation.
- Dizziness.
- Depression.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Take Epimate at about the same time each day
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Epimate.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Drink plenty of water.
- Epimate has been known to cause kidney stones and drinking water may help prevent this.

- Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give Epimate to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of *Suicidal thoughts and behavior*

Medicines used to treat epilepsy can increase the risk of suicidal thoughts and behavior. If you experience feelings of deep sadness and unworthiness (depression) or a worsening of these feelings, any unusual changes in your mood or the emergence of suicidal thoughts, behavior or thoughts of self harm, you should report this to your doctor immediately.

Driving and using machines

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

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Tell your doctor if any of the following continue or worry you:

- Unusual tiredness.
- Drowsiness.
- Weakness.
- Dizziness.
- Decrease in appetite or weight loss.
- Itchy skin or skin rash.
- Inability to sleep.
- Headache.
- Tingling and numbness of hands and feet.
- Nose bleed.
- Nausea, constipation, viral infection.
- Decreased or lack of sweating.

Tell your doctor as soon as possible if you have any of the following as you may need medical attention:

- Nervousness or feeling anxious.
- Disturbance in attention.
- Hearing decreased.
- Difficulty with memory or memory impairment.
- Slowing of thought processes.
- Abnormal behaviour.
- Expressive language disorder.
- Balance disorder, coordination problems.
- Unusual hair loss or thinning.

- Abnormal frequent urination.
- 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.
- Toxic epidermal necrosis characterized by widespread blistering and sloughing of the outer layers of the skin.
- Hepatic failure (including fatalities), hepatitis.
- Fever or high temperature.
- Pneumonia.
- Difficulty in speaking.
- Pancreatitis (inflammation of the pancreas).
- Vision abnormal.

Tell your doctor immediately if you have:

- Kidney stones.
- Pain when passing urine.
- Sudden changes in your eyesight (e.g. Blurred or loss of vision) or rapid uncontrollable movements of the eyes.
- Eye pain.
- Red eye.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

There is a potential significant risk for metabolic acidosis that may have no symptoms and if left untreated may be associated with adverse effects of kidneys (e.g. kidney stone/nephrocalcinosis). If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Epimate

- Storage

- Store below 30°C.

EPIMATE TABLET

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- Disposal

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.

Product Description

- What it looks like

EPIMATE 50 TABLET:

Yellow colored, round, biconvex, film coated tablets debossed with breakline on both sides separating '10' and '32' on one side and '50' on other side.

EPIMATE 100 TABLET:

Light yellow colored, round, biconvex, film coated tablets debossed with breakline on both sides separating '10' and '33' on one side and '100' on other side.

- Ingredients

Active ingredient

- Topiramate.

Inactive ingredients

- Lactose monohydrate.
- Microcrystalline cellulose.
- Pregelatinized starch.
- Sodium starch glycolate.
- Colloidal silicon dioxide.
- Talc.
- Magnesium stearate.
- Hypromellose 2910
- Polyethylene glycol 400.
- Titanium dioxide.

- MAL number(s):

EPIMATE 50 TABLET:

MAL10053664AZ

EPIMATE 100 TABLET:

MAL10053666AZ

Manufacturer

Torrent Pharmaceuticals Limited Indrad
382 721, Tal: Kadi,
City: Indrad, Dist. Mehsana, India

Product Registration Holder

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