

MEDICATION GUIDE

Topiramate (TOE-pee-rah-mate) Tablets USP

Read this Medication Guide before you start taking topiramate and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about topiramate talk to your healthcare provider or pharmacist

What is the most important information I should know about topiramate tablets ?

- **Topiramate tablets may cause eye problems.**

Serious eye problems include:

- any sudden decrease in vision with or without eye pain and redness,
- a blockage of fluid in the eye causing increased pressure in the eye (secondary angle closure glaucoma).
- These eye problems can lead to permanent loss of vision if not treated. You should call your healthcare provider right away if you have any new eye symptoms.
- **Topiramate tablets may cause decreased sweating and increased body temperature (fever).** People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalized for this condition.
- **Like other antiepileptic drugs, topiramate may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Do not stop topiramate without first talking to a healthcare provider.

- Stopping topiramate suddenly can cause serious problems.
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes .

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Topiramate can harm your unborn baby.

- If you take topiramate during pregnancy, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant.
- Cleft lip and cleft palate may happen even in children born to women who are not taking any medicines and do not have other risk factors.
- There may be other medicines to treat your condition that have a lower chance of birth defects.
- All women of childbearing age should talk to their healthcare providers about using other possible treatments instead of topiramate. If the decision is made to use topiramate, you should use effective birth control (contraception) unless you are planning to become pregnant. You should talk to your doctor about the best kind of birth control to use while you are taking topiramate.
- Tell your healthcare provider right away if you become pregnant while taking topiramate. You and your healthcare provider should decide if you will continue to take topiramate while you are pregnant.
- Pregnancy Registry: If you become pregnant while taking topiramate, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.

What is topiramate?

Topiramate is a prescription medicine used:

- to treat certain types of seizures (partial onset seizures and primary generalized tonic-clonic seizures) in people 10 years and older,
- with other medicines to treat certain types of seizures (partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome) in adults and children 2 years and older.

What should I tell my healthcare provider before taking Topiramate Tablets?

Before taking topiramate, tell your healthcare provider about all your medical conditions, including if you:

- have or have had depression, mood problems or suicidal thoughts or behavior
- have kidney problems, have kidney stones, or are getting kidney dialysis
- have a history of metabolic acidosis (too much acid in the blood)
- have liver problems
- have osteoporosis, soft bones, or decreased bone density
- have lung or breathing problems
- have eye problems, especially glaucoma
- have diarrhea
- have a growth problem
- are on a diet high in fat and low in carbohydrates, which is called a ketogenic diet
- are having surgery
- are pregnant or plan to become pregnant

- are breastfeeding. Topiramate passes into breast milk. It is not known if the topiramate that passes into breast milk can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take topiramate.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Topiramate and other medicines may affect each other causing side effects

Especially, tell your healthcare provider if you take:

- Valproic acid (DEPAKENE[®], DEPAKOTE[®])
- any medicines that impair or decrease your thinking, concentration, or muscle coordination.
- birth control pills. Topiramate may make your birth control pills less effective. Tell your healthcare provider if your menstrual bleeding changes while you are taking birth control pills and topiramate.

Ask your healthcare provider if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine. Do not start a new medicine without talking with your healthcare provider.

How should I take Topiramate Tablets?

- Take topiramate tablets exactly as prescribed.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Topiramate tablets should be swallowed whole. Do not chew the tablets. They may leave a bitter taste.
- Do not store any medicine and food mixture for later use.
- Topiramate tablets can be taken before, during, or after a meal. Drink plenty of fluids during the day. This may help prevent kidney stones while taking topiramate.
- If you take too much topiramate, call your healthcare provider or poison control center right away or go to the nearest emergency room.
- If you miss a single dose of topiramate, take it as soon as you can. However, if you are within 6 hours of taking your next scheduled dose, wait until then to take your usual dose of topiramate, and skip the missed dose. Do not double your dose. If you have missed more than one dose, you should call your healthcare professional for advice.
- Do not stop taking topiramate without talking to your healthcare provider. Stopping topiramate suddenly may cause serious problems. If you have epilepsy and you stop taking topiramate suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking topiramate slowly.
- Your healthcare provider may do blood tests while you take topiramate.

What should I avoid while taking topiramate tablets?

- Do not drink alcohol while taking topiramate. Topiramate and alcohol can affect each other causing side effects such as sleepiness and dizziness.
- Do not drive a car or operate heavy machinery until you know how topiramate affects you. Topiramate can slow your thinking and motor skills, and may affect vision.

What are the possible side effects of topiramate tablets?

Topiramate may cause serious side effects including:

See [“What is the most important information I should know about topiramate tablets?”](#)

- **Metabolic Acidosis.** Metabolic acidosis can cause:
 - tiredness
 - loss of appetite
 - irregular heartbeat

- impaired consciousness
 - **High blood ammonia levels.** High ammonia in the blood can affect your mental activities, slow your alertness, make you feel tired, or cause vomiting. This has happened when topiramate is taken with a medicine called valproic acid (DEPAKENE[®] and DEPAKOTE[®]).
 - **Kidney stones.** Drink plenty of fluids when taking topiramate to decrease your chances of getting kidney stones.
 - **Effects on Thinking and Alertness.** Topiramate may affect how you think, and cause confusion, problems with concentration, attention, memory, or speech. Topiramate may cause depression or mood problems, tiredness, and sleepiness.
 - **Dizziness or Loss of Muscle Coordination.**
- Call your healthcare provider right away if you have any of the symptoms above.

The most common side effects of topiramate include:

- tingling of the arms and legs (paresthesia)
- not feeling hungry
- nausea
- a change in the way foods taste
- diarrhea
- weight loss
- nervousness
- upper respiratory tract infection

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of topiramate. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Glenmark Generics Inc., USA at 1-888(721)-7115 or www.glenmarkgenerics.com

How should I store Topiramate tablets ?

- Store topiramate tablets at room temperature, 20-25°C (68-77°F).
- Keep topiramate in a tightly closed container.
- Keep topiramate dry and away from moisture.

Keep topiramate and all medicines out of the reach of children

General information about topiramate

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use topiramate for a condition for which it was not prescribed. Do not give topiramate to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about topiramate. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about topiramate that is written for health professionals.

For more information, go to www.glenmarkgenerics.com or call 1 (888)721-7115

What are the ingredients in topiramate tablets USP?

Active ingredient: topiramate USP

Inactive ingredients:

lactose monohydrate, pregelatinized starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, purified water, hypromellose, titanium dioxide, polyethylene glycol, iron oxide (50,100 and 200 mg tablets)and polysorbate 80

Manufactured by:

Glenmark Generics Ltd.

Colvale-Bardez, Goa 403 513, India

Manufactured for:



Glenmark Generics Inc., USA

Mahwah, NJ 07430

Questions? 1 (888)721-7115

www.glenmarkgenerics.com

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This Medication Guide has been approved by the U.S. Food and Drug Administration