

## MEDICATION GUIDE

### TOPIRAMATE TABLETS

Read this Medication Guide before you start taking topiramate tablets 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 tablets, 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, fever, especially in hot temperatures. Some people may need to be hospitalized for this condition.
- **Like other antiepileptic drugs, topiramate tablets 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 tablets without first talking to a healthcare provider.

- Stopping topiramate tablets 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.

#### What are topiramate tablets?

Topiramate tablets are 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 tablets, 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, 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. It is not known if topiramate tablets will harm your unborn baby. If you become pregnant while taking topiramate tablets, 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 medicine during pregnancy.
- are breastfeeding. It is not known if topiramate passes into breast milk and if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take topiramate tablets.

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

Especially, tell your healthcare provider if you take:

- Valproic acid (Depakene<sup>®</sup>, Depakote<sup>®</sup>)
- any medicines that impair or decrease your thinking, concentration, or muscle coordination.
- birth control pills. Topiramate tablets 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 tablets.

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.
- 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 tablets.
- If you take too many topiramate tablets, 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 tablets, 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 tablets, 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 tablets without talking to your healthcare provider. Stopping topiramate tablets suddenly may cause serious problems. If you have epilepsy and you stop taking topiramate tablets suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking topiramate tablets slowly.
- Your healthcare provider may do blood tests while you take topiramate tablets.

#### **What should I avoid while taking topiramate tablets?**

- Do not drink alcohol while taking topiramate tablets. Topiramate tablets 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 tablets affect you. Topiramate tablets can slow your thinking and motor skills.

#### **What are the possible side effects of topiramate tablets?**

Topiramate tablets 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 tablets is taken with a medicine called valproic acid (DEPAKENE® and DEPAKOTE®).
- **Kidney stones.** Drink plenty of fluids when taking topiramate tablets to decrease your chances of getting kidney stones.
- **Effects on Thinking and Alertness.** Topiramate tablets may affect how you think, and cause confusion, problems with concentration, attention, memory, or speech. Topiramate tablets 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 tablets 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 tablets. 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.

#### **How should I store topiramate tablets?**

- Store topiramate tablets at room temperature, 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
- Keep topiramate tablets in a tightly closed container
- Keep topiramate tablets dry and away from moisture
- **Keep topiramate tablets and all medicines out of the reach of children.**

#### **General information about topiramate tablets.**

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

This Medication Guide summarizes the most important information about topiramate tablets. If you would like more information, talk with your healthcare provider.

You can ask your pharmacist or healthcare provider for information about topiramate tablets that is written for health professionals.

#### **What are the ingredients in topiramate tablets?**

**Active ingredient:** topiramate

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

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