

Medication Guide

Topiramate Capsules (Sprinkle) (toe pir' a mate)

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

Topiramate 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, including any new problems with your vision.

Topiramate 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. If a high fever, a fever that does not go away, or decreased sweating develops, call your healthcare provider right away.

Topiramate can increase the level of acid in your blood (metabolic acidosis). If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones, can slow the rate of growth in children, and may possibly harm your baby if you are pregnant. Metabolic acidosis can happen with or without symptoms.

Sometimes people with metabolic acidosis will:

- feel tired
- feel changes in heartbeat
- not feel hungry (loss of appetite)
- have trouble thinking clearly

Your healthcare provider should do a blood test to measure the level of acid in your blood before and during your treatment with topiramate. If you are pregnant, you should talk to your healthcare provider about whether you have metabolic acidosis.

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
- trouble sleeping (insomnia)
- attempts to commit suicide
- new or worse irritability
- new or worse depression
- acting aggressive, being angry, or violent
- new or worse anxiety
- acting on dangerous impulses

- feeling agitated or restless
- an extreme increase in activity and talking (mania)
- panic attacks
- 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 including cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant.
- Birth defects 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.
- If you take topiramate during pregnancy, your baby may be smaller than expected at birth. The long-term effects of this are not known. Talk to your healthcare provider if you have questions about this risk during pregnancy.
- Metabolic acidosis may have harmful effects on your baby. Talk to your healthcare provider if topiramate has caused metabolic acidosis during your pregnancy.
- 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 topiramate and other antiepileptic drugs during pregnancy.

Topiramate may decrease the density of bones when used over a long period.

Topiramate may slow height increase and weight gain in children and adolescents when used over a long period.

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 adults and children 2 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,
- to prevent migraine headaches in adults and adolescents 12 years and older.

Who should not take topiramate?

Do not take topiramate if you are allergic to topiramate, or any of the ingredients in topiramate. See the end of this Medication Guide for a complete list of ingredients in topiramate.

Before taking topiramate, tell your healthcare provider about all of 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 weak, brittle, or soft bones (osteomalacia, osteoporosis, osteopenia, 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 or plan to breastfeed. Topiramate passes into breast milk. Breastfed babies may be sleepy or have diarrhea. It is not known if the topiramate that passes into breast milk can cause other serious harm to 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 over-the-counter 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 (such as DEPAKENE or DEPAKOTE).
- any medicines that impair or decrease your thinking, concentration, or muscle coordination.
- birth control that contains hormones (such as pills, implants, patches or injections). Topiramate may make your birth control less effective. Tell your healthcare provider if your menstrual bleeding changes while you are using birth control 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?

- Take topiramate exactly as prescribed.
- Your healthcare provider may change your dose. **Do not** change your dose without talking to your healthcare provider.
- Topiramate capsules (sprinkle) may be swallowed whole or may be opened and sprinkled on a teaspoon of soft food. Drink fluids right after eating the food and medicine mixture to make sure it is all swallowed. **Do not** chew the food and medicine mixture.
- **Do not** store any medicine and food mixture for later use.
- Topiramate 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 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 provider 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?

- You should 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 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?

Topiramate may cause serious side effects including:

See “**What is the most important information I should know about topiramate?**”

- **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.**
- **Severe multiorgan reactions.** Treatment with topiramate may cause a serious allergic reaction that may affect

your skin or other parts of your body such as your liver, kidneys, heart, or blood cells. This allergic reaction can be life-threatening and can cause death, particularly if it is not treated as early as possible. Contact your healthcare provider or get medical help right away if you have:

- blistering and peeling of your skin or skin rash
- fever or swollen glands that do not go away
- hives
- swelling of your face, eyes, lips, tongue, or throat
- sores in your mouth,
- trouble swallowing or breathing
- dark urine
- yellowing of the skin or whites of the eyes
- **Serious skin reactions.** Topiramate may cause a severe rash with blisters and peeling skin, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome). Topiramate may also cause a rash with blisters and peeling skin over much of the body that may cause death (toxic epidermal necrolysis). Call your healthcare provider right away if you develop a skin rash or blisters.
- **Allergic reactions.** Serious allergic reactions can happen after you take topiramate. Get emergency help right away if you have swelling of the face, lips, eyes, tongue, or throat, or trouble swallowing or breathing.
- **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 (DEPAKOTE). Call your healthcare provider right away if you develop unexplained tiredness, vomiting, slowing of your thinking or reaction time, or changes in your mental activities.
- **Kidney stones.** Drink plenty of fluids when taking topiramate to decrease your chances of getting kidney stones.
- **Low body temperature.** Taking topiramate when you are also taking valproic acid can cause a drop in body temperature to less than 95°F, or can cause tiredness, confusion, or coma.

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)
- nervousness
- upper respiratory tract infection
- slow reactions
- difficulty with memory
- not feeling hungry
- pain in the abdomen
- nausea
- speech problems
- fever
- a change in the way foods taste
- tiredness

- abnormal vision
- dizziness
- decreased feeling or sensitivity, especially in the skin
- diarrhea
- sleepiness/drowsiness
- weight loss

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. 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 Strides Pharma Inc. at 1-877-244-9825.

How should I store topiramate?

- Store topiramate at room temperature between 20° to 25°C (68° to 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 the safe and effective use of 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.

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

What are the ingredients in topiramate capsules (sprinkle)?

Active ingredient: topiramate

Inactive ingredients:

- **Capsules (sprinkle):** carboxymethylcellulose calcium, FD&C Red No. 40, gelatin, hypromellose, lactose monohydrate, microcrystalline cellulose, polyethylene glycol, povidone, saccharin sodium, sodium lauryl sulfate, talc and titanium dioxide. The imprinting ink contains shellac, black iron oxide and traces of potassium hydroxide.

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For more information, call contact Strides Pharma Inc. at 1-877-244-9825 or go to www.strides.com

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