

MEDICATION GUIDE

TOPAMAX[®] (TOE-PA-MAX) (topiramate)

Tablets and Sprinkle Capsules

Read this Medication Guide before you start taking TOPAMAX[®] 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 TOPAMAX[®], talk to your healthcare provider or pharmacist.

What is the most important information I should know about TOPAMAX[®]?

TOPAMAX[®] 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.

TOPAMAX[®] 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.

TOPAMAX[®] 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
- not feel hungry (loss of appetite)
- feel changes in heartbeat
- 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 TOPAMAX[®]. If you are pregnant, you should talk to your healthcare provider about whether you have metabolic acidosis.

Like other antiepileptic drugs, TOPAMAX[®] 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 TOPAMAX[®] without first talking to a healthcare provider.

- Stopping TOPAMAX[®] 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.

TOPAMAX[®] can harm your unborn baby.

- If you take TOPAMAX[®] 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 TOPAMAX[®]. If the decision is made to use TOPAMAX[®], 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 TOPAMAX[®].
- Tell your healthcare provider right away if you become pregnant while taking TOPAMAX[®]. You and your healthcare provider should decide if you will continue to take TOPAMAX[®] while you are pregnant.
- Metabolic acidosis may have harmful effects on your baby. Talk to your healthcare provider if TOPAMAX[®] has caused metabolic acidosis during your pregnancy.
- Pregnancy Registry: If you become pregnant while taking TOPAMAX[®], 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 TOPAMAX[®]?

TOPAMAX[®] 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.

What should I tell my healthcare provider before taking TOPAMAX[®]?

Before taking TOPAMAX[®], 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 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. TOPAMAX[®] passes into breast milk. It is not known if the TOPAMAX[®] 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 TOPAMAX[®].

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. TOPAMAX[®] 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 pills. TOPAMAX[®] 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 TOPAMAX[®].

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 TOPAMAX[®]?

- Take TOPAMAX[®] exactly as prescribed.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- TOPAMAX[®] Tablets should be swallowed whole. Do not chew the tablets. They may leave a bitter taste.

- TOPAMAX[®] Sprinkle Capsules 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 store any medicine and food mixture for later use.
- TOPAMAX[®] can be taken before, during, or after a meal. Drink plenty of fluids during the day. This may help prevent kidney stones while taking TOPAMAX[®].
- If you take too much TOPAMAX[®], call your healthcare provider or poison control center right away or go to the nearest emergency room.
- If you miss a single dose of TOPAMAX[®], 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 TOPAMAX[®], 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 TOPAMAX[®] without talking to your healthcare provider. Stopping TOPAMAX[®] suddenly may cause serious problems. If you have epilepsy and you stop taking TOPAMAX[®] suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking TOPAMAX[®] slowly.
- Your healthcare provider may do blood tests while you take TOPAMAX[®].

What should I avoid while taking TOPAMAX[®]?

- Do not drink alcohol while taking TOPAMAX[®]. TOPAMAX[®] 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 TOPAMAX[®] affects you. TOPAMAX[®] can slow your thinking and motor skills, and may affect vision.

What are the possible side effects of TOPAMAX[®]?

TOPAMAX[®] may cause serious side effects including:

See “What is the most important information I should know about TOPAMAX[®]?”

- **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

TOPAMAX[®] is taken with a medicine called valproic acid (DEPAKENE[®] and DEPAKOTE[®]).

- **Low body temperature:** Taking TOPAMAX[®] when you are also taking valproic acid can cause a drop in body temperature to less than 95⁰F, feeling tired, confusion, or coma.
- **Kidney stones.** Drink plenty of fluids when taking TOPAMAX[®] to decrease your chances of getting kidney stones.
- **Effects on thinking and alertness.** TOPAMAX[®] may affect how you think and cause confusion, problems with concentration, attention, memory, or speech. TOPAMAX[®] 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 TOPAMAX[®] 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 TOPAMAX[®]. 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 Janssen Pharmaceuticals, Inc. at 1-800-JANSSEN (1-800-526-7736).

How should I store TOPAMAX[®]?

- Store TOPAMAX[®] Tablets at room temperature, 59°F to 86°F (15°C to 30°C).
- Store TOPAMAX[®] Sprinkle Capsules at or below 77°F (25°C).

- Keep TOPAMAX[®] in a tightly closed container.
- Keep TOPAMAX[®] dry and away from moisture.
- **Keep TOPAMAX[®] and all medicines out of the reach of children.**

General information about TOPAMAX[®].

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TOPAMAX[®] for a condition for which it was not prescribed. Do not give TOPAMAX[®] 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 TOPAMAX[®]. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TOPAMAX[®] that is written for health professionals.

For more information, go to www.topamax.com or call 1-800-JANSSEN (1-800-526-7736).

What are the ingredients in TOPAMAX[®]?

Active ingredient: topiramate

Inactive ingredients:

- **Tablets** - lactose monohydrate, pregelatinized starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, purified water, carnauba wax, hypromellose, titanium dioxide, polyethylene glycol, synthetic iron oxide, and polysorbate 80.
- **Sprinkle Capsules** - sugar spheres (sucrose and starch), povidone, cellulose acetate, gelatin, sorbitan monolaurate, sodium lauryl sulfate, titanium dioxide, and black pharmaceutical ink.

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

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