

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.

- **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.

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 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
- 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, 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 TOPAMAX will harm your unborn baby. 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 medicine during pregnancy.

- are breastfeeding. It is not known if TOPAMAX 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 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 (Depakene, 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 professional 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.

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).
- **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.

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 25°C (77°F).
- 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 1-800-526-7736.

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, sodium lauryl sulfate, titanium dioxide, and black pharmaceutical ink.

Manufactured by: Janssen Ortho, LLC Gurabo, Puerto Rico 00778

Manufactured for: (LOGO) Ortho-McNeil Neurologics

Ortho-McNeil Neurologics, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.
Titusville, NJ

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