

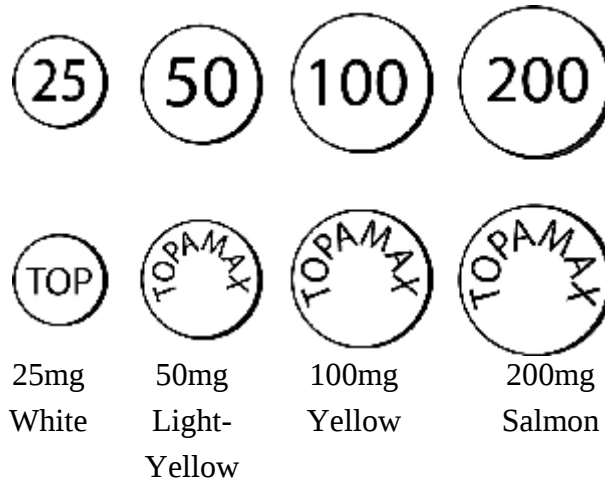
PATIENT INFORMATION

TOPAMAX® [Toe-pa-max.]

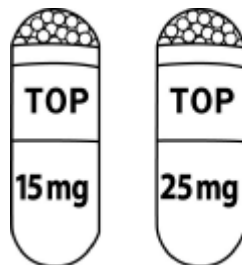
(topiramate) Tablets/(topiramate capsules) Sprinkle Capsules

What do TOPAMAX Tablets and Sprinkle Capsules look like?

TOPAMAX® (topiramate) Tablets



TOPAMAX® (topiramate capsules) Sprinkle Capsules



Capsules are white and clear.

Note: The pictures above show the shapes and lettering of TOPAMAX tablets and sprinkle capsules. The wording describes the strength and colors of the medication. Before taking your medicine, it is important to compare the tablets or sprinkle capsules you receive from your healthcare professional or pharmacist with these pictures to make sure you have received the correct medicine.

Please read this patient information carefully before you take TOPAMAX and each time you obtain a refill, in case any information has changed. This summary does not contain all the information about TOPAMAX and is not meant to take the place of talking with your healthcare professional. If you have any questions about TOPAMAX, discuss them with your healthcare professional

or pharmacist.

What is TOPAMAX?

TOPAMAX is a prescription medicine used:

- alone to treat seizures in patients 10 years and older
- with other medicines to treat seizures in adults and children over age 2
- to prevent migraine headaches in adults

Who Should Not Take TOPAMAX?

Do not take TOPAMAX if you are allergic to anything in it. See the end of this leaflet for a complete list of ingredients in TOPAMAX.

What Should I Tell My Healthcare Professional Before Taking TOPAMAX?

Tell your healthcare professional about all of your medical conditions, including if you:

- have kidney problems, especially kidney stones, or are getting kidney dialysis
- have a history of metabolic acidosis (blood and body fluid abnormality)
- have liver problems
- have osteoporosis (weak or brittle bones) and/or soft bones (osteomalacia) or decreased bone density (osteopenia)
- have lung or breathing problems
- have eye problems, especially glaucoma
- have diarrhea
- have a growth problem
- are on a diet high in fat called a ketogenic diet
- are having surgery
- are pregnant or planning to become pregnant. It is not known if TOPAMAX can harm your unborn baby.
- are breastfeeding. TOPAMAX may pass into your milk. Talk to your healthcare professional about the best way to feed your baby while taking TOPAMAX.
- suffer from depression, mood problems or suicidal thoughts or behavior

Tell your healthcare professional about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements.

TOPAMAX and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or TOPAMAX will have to be adjusted. Especially, tell your healthcare professional if you are taking:

- **other medicines that impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines).**
- **birth control pills.** TOPAMAX may make your birth control pills less effective. Tell your healthcare professional if your menstrual bleeding changes while you are taking birth control pills and TOPAMAX.

Keep a list of all the medicines you take. Show this list to your healthcare professionals and pharmacists before you start a new medicine.

How Should I Take TOPAMAX?

- Take TOPAMAX exactly as prescribed. Your healthcare professional will usually start you on a low dose of TOPAMAX and slowly increase your dose until the best dose is found for you.
- TOPAMAX Tablets should be swallowed whole. Avoid, chewing the tablets as 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 of any type. Examples are applesauce, custard, ice cream, oatmeal, pudding or yogurt. Drink fluids right after to make sure all of the food and medicine mixture is swallowed.
- Never store any medicine and food mixture for use at a later time.
- TOPAMAX can be taken before, during, or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking TOPAMAX.
- If you take too much TOPAMAX, call your healthcare professional or poison control center right away or go to an 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 unless a healthcare professional tells you to stop taking TOPAMAX. Your healthcare professional will tell you how to slowly stop taking TOPAMAX.

What Should I Avoid While Taking TOPAMAX?

- If you are taking Topamax or other antiepileptic drugs for epilepsy or seizures, you may need to avoid activities where loss of consciousness (passing out) could result in serious danger to yourself or those around you (including swimming, driving a car, climbing in high places, etc.). Talk to

your doctor before engaging in such activities.

- Unless prescribed by your healthcare professional, you should avoid other medicines that also impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines).
- You should avoid drinking alcohol while taking TOPAMAX. Alcohol with TOPAMAX can make side effects such as sleepiness and dizziness worse.
- Do not drive a car or operate heavy machinery until you know how TOPAMAX affects you. TOPAMAX can impair your thinking and motor skills.

What are the Possible Side Effects of TOPAMAX?

TOPAMAX may cause the following side effects which can be serious :

- **metabolic acidosis.** Metabolic acidosis is a condition that happens when there is too much acid in your blood. Metabolic acidosis can cause symptoms such as tiredness, loss of appetite, irregular heartbeat, and impaired consciousness. **Call your healthcare professional right away if you get these symptoms with TOPAMAX.** Your healthcare professional should do a blood test (measurement of serum bicarbonate) to monitor your bicarbonate level while you are taking TOPAMAX.
- **eye problems.** Serious eye problems include:
 - a sudden decrease in vision (acute myopia) with or without eye pain and
 - a blockage of fluid in the eye causing increased pressure in the eye (secondary angle closure glaucoma).

Call your healthcare professional right away if you have a loss in vision or get eye pain. These problems can lead to blindness if not treated right away. Your healthcare professional will probably stop TOPAMAX and may recommend other therapy.

- **decreased sweating (oligohidrosis) and increased body temperature (fever).** Patients, especially children, should be watched closely for signs of decreased sweating and fever (increased body temperature), especially in hot temperatures. Some patients may need hospital treatment for this condition.
- **effects on thinking and alertness.** TOPAMAX may affect thinking skills and cause confusion, problems with concentration, attention, memory, and/or speech. TOPAMAX may cause depression or mood problems, tiredness, and sleepiness. Call your healthcare professional right away if you experience any of these side effects.
- **dizziness or loss of muscle coordination** in patients who take TOPAMAX alone or with other seizure medicines.
- **high blood ammonia levels and effects on mental activities.** High

ammonia in the blood can affect your mental activities and decrease alertness, can make you feel tired or fatigued, or can cause vomiting. This has happened when TOPAMAX has been used 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.
- **tingling of the arms and legs (paresthesia)** is a common side effect of TOPAMAX.

Other side effects with TOPAMAX include loss of appetite, nausea, a change in the way foods taste, diarrhea, weight loss, nervousness, aggression, upper respiratory tract infection.

Call your healthcare professional if you have any symptoms that concern you or that do not go away.

These are not all the side effects with TOPAMAX. For more information, ask your healthcare professional or pharmacist.

What Should I Do If I Get Pregnant While Taking TOPAMAX?

It is not clear if there is a risk to the fetus/baby if you are exposed to TOPAMAX and you are pregnant. Various abnormalities have been described in the offspring of animals exposed to TOPAMAX during pregnancy. If you use TOPAMAX while you are pregnant, ask your healthcare professional about reporting your experience to the North American Drug Pregnancy Registry at Massachusetts General Hospital (Boston, MA). This registry collects information about the babies born to women who are taking drugs to treat various conditions. Information about the North American Drug Pregnancy Registry can be found at <http://www.massgeneral.org/aed/>. You can also join the registry by calling 1-877-376-3872.

How Should I Store TOPAMAX?

- Store TOPAMAX tablets in tightly-closed containers at room temperature, 59°F to 86°F (15°C to 30°C). Protect from moisture.
- Store TOPAMAX Sprinkle Capsules in tightly-closed containers at or below 77°F (25°C). Protect 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 Patient Information leaflets. 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 leaflet summarizes the most important information about TOPAMAX. If you would like more information, talk to your healthcare professional. You can ask your health care professional or pharmacist for information about TOPAMAX that is written for health professionals. You can also visit www.topamax.com or call 1-888-TOPAMAX (1-888-867-2629) for more information.

What Are the Ingredients of TOPAMAX?

Active Ingredient: topiramate

Inactive Ingredients:

- **Tablets** - contain lactose monohydrate, pregelatinized starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, purified water, carnauba wax, hypromellose, titanium dioxide, polyethylene glycol, synthetic iron oxide (100 and 200 mg tablets) and polysorbate 80.
- **Sprinkle Capsules** - contain sugar spheres (sucrose and starch), povidone, cellulose acetate, gelatin, sorbitan monolaurate, sodium lauryl sulfate, titanium dioxide, and black pharmaceutical ink.

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