

Patient Name: _____ **Date:** _____
Doctor Name: _____ **Emergency Number:** _____
Pharmacy: _____ **Number:** _____

What is Topiramate?

Topiramate (also known as Topamax) is a medicine that has been approved by the Food and Drug Administration to treat partial and generalized tonic clonic seizures and seizures associated with Lennox-Gastaut syndrome in adults and children over 2 years of age. Topiramate can also be used alone as a first treatment for seizures in adults and children 10 years of age or older with partial seizures or primary generalized tonic clonic seizures.

- Topiramate has been approved to prevent migraine headaches in adults.
- Topiramate is excreted by the kidneys and the dose or the way it is taken may be different in people with kidney problems.
- Topiramate is not available in generic form yet in the United States. Generic forms may be available in other countries and may look different, depending on the company that makes the generic.
- The dose of topiramate and how it is taken may vary depending on why it is being given, the form of medicine, and whether it is taken alone or with other medicines. It is important to follow the exact directions given to you by your doctor.
- Always check the appearance of the tablets with the pharmacist when the prescription is filled to be certain you are given the right medication.

Important questions to ask your doctor:

- Why am I being given this medicine? _____
- What amount should I be taking? _____

What does the drug look like and how should I take it?

Topamax Tablets

Available in four strengths:

25 mg (cream)

Marked with "25" on one side and "OMN" on the other



25mg

50 mg (light yellow)

Tablets marked "50" on one side and "OMN" on the other



50mg

100 mg (yellow)

Marked with "100" on one side and "OMN" on the other



100mg

200 mg (salmon)

Marked with "200" on one side and "OMN" on the other



200mg

To take tablets:

- Swallow the tablets whole with a glass of water.
- Tablets have a bitter taste - do not crush, chew or bite the tablets.
- Usually taken two or more times a day.

Topamax Sprinkle Capsules

Available in two strengths:

15 mg (white, clear gelatin capsule with white to off-white beads)
Marked with "TOP" and "15 mg" on one side



15mg

25 mg (white, clear gelatin capsule with white to off-white beads)
Marked with "TOP" and "25" on one side



25mg

To take capsules:

- To sprinkle the capsule contents:
 - Open capsule by holding it upright so you can read the word TOP.
 - Twist off the clear part of the capsule.
 - Sprinkle the capsule contents onto a teaspoon of soft food, such as applesauce or pudding.
 - Mix the drug with the food.
 - Swallow all the mixture right away
 - do not chew it.
 - Drink water or fluid afterwards to make sure all mixture has been swallowed.
 - Do not save any of the mixture for later use.
- Usually taken twice a day.

Frequently Asked Questions:

Is it best to take this medicine with food? This medicine can be taken with food or on an empty stomach. Sometimes taking it with food will lessen stomach upset. Try to take it the same way each day, since taking this with food may change the time it takes to be absorbed.

What should I do if I miss a dose? If you miss or forget a dose, talk to your doctor for specific instructions on how to make it up. Do not double up or take extra medicine, unless instructed to do so by your doctor.

How can I remember to take my medicine?

- Take medicine at the same time each day.
- Take medicine at the same times as some other routine, such as brushing teeth, after meals, or bedtime.
- Use a pillbox so you can check if you have taken a dose.
- Use an alarm to remind yourself of times to take a dose.
- Keep a written schedule or chart of when to take the medicine.
- Talk to your doctor or health care provider about problems remembering to take the medicine.

How long will it take for the medicine to work? It may take a number of weeks to find the right dose, and then more time may be needed to know how well the medicine works to control your seizures. How long this takes will be different for each person. It may depend on how often you have seizures, what other medicine you may be taking, and how your body responds to the drug.

Should I write down how the medicine is affecting me? It is important to write down how you feel while you are on the medicine. Also keep track of changes in how much medicine is prescribed, side effects, and changes in seizures. Take the information to all follow-up visits with your health care providers.

How should I store my medicine? Store Topomax tablets at room temperature (59°F to 86°F or 15° C to 30° C), away from heat, moisture, and direct light. Be sure to protect the sprinkle capsules from heat and store below 77°F (25°C). Keep all medicine out of the reach of children. Don't keep in the bathroom, glove box of a car, or where children can easily find them, such as in purses or low cabinets or counter top for example.

Will this medicine affect other medicines that I am taking? Make sure to tell all your health care providers the names of all medicines, herbal or dietary supplements, vitamins and over-the-counter medicines you may be taking. Some of these medicines may interfere with how topiramate works and lower or raise the amount in your system.

For example, topiramate may interact with hormonal contraceptives and other antiepileptic medicines. Topiramate may increase the level of phenytoin in the body. Other seizure medicines (including phenytoin, carbamazepine, phenobarbital, primidone) may lower the level of topiramate in the body. Topiramate may also interact with medications used for psychiatric conditions.

What side effects may occur? Side effects may occur with any medicine. Some side effects will go away on their own or when the dose of medicine is changed. Others may be more serious and mean that your body is not tolerating the drug. Most people who take topiramate have no side effects or only mild to moderate side effects that do not cause long term problems. However, just like with any medicine, a very small number of people may have a serious reaction. Tell your doctor about all side effects that occur, but do not stop taking the medicine without advice from your doctor. Some side effects include the following:

Common: Tired, drowsy, difficulty concentrating, difficulty finding the right word or words to say, confusion, dizziness, unsteady, feeling of pins and needles in the tips of the fingers and toes, loss of appetite, weight loss.

Less common: Feeling nervous, depression, difficulty with memory.

Potentially 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 these symptoms develop while taking topiramate. Talk to your doctor about when you should have a blood test done to measure the amount of bicarbonate or acid in your blood.
- **Glaucoma:** Call your doctor immediately if you have blurred vision or difficulty seeing that comes on quickly, possibly with eye pain. If these symptoms occur, they typically do so during the first month of taking topiramate.
- **Kidney Stones:** Kidney stones are most likely to occur in men, people with a family history of kidney stones, people who themselves have had kidney stones in the past, or people who are also using acetazolamide, zonisamide, or the ketogenic diet. Symptoms of kidney stones may include: sharp pains in the side or lower back, blood in urine or difficulty urinating.
- **Inadequate sweating:** Some children who take topiramate may not sweat enough in hot weather and their body temperatures may rise, sometimes to dangerous levels. Children taking topiramate should be checked in hot weather to be sure they sweat appropriately
- **Rash:** Not all rashes are caused by the medicine, but all rashes should be reported to your doctor and checked out. Rashes that may be more serious usually begin in the first few weeks, but can happen at any time while you are on the drug. Serious rashes may have the following symptoms and require immediate evaluation:
 - Blisters or sores in mouth, eyes, ears, nose, and genital area.
 - Swelling of eyelids or red eyes.
 - Red spots or patches on skin.
 - Fever or flu-like symptoms that don't go away.
- **Allergic reaction:** May be seen with symptoms such as hives or large red spots on the body, itching, difficulty breathing or closing of the throat.

On July 10, 2008, an advisory panel was convened by the Food and Drug Administration (FDA) to review data that the FDA had previously collected from drug studies showing an association between many of the antiepileptic drugs (AEDs) and suicidal ideation and behavior, which together are called suicidality. According to the FDA's Alert, among the patients with epilepsy in these drug studies, 1 out of 1000 people taking the placebo (inactive substance) showed suicidality compared to approximately 3.5 out of 1000 people who took an AED. The FDA advisory panel voted to accept the FDA's data at its meeting on July 10.

The FDA has provided the following information for patients, family members, and caregivers at www.fda.gov/cder/drug/InfoSheets/HCP/antiepilepticsHCP.htm:

- Taking antiepileptic medicines may increase the risk of having suicidal thoughts or actions;
- Do not make any changes to the medication regimen without first talking with the responsible healthcare professional;

- Pay close attention to any day-to-day changes in mood, behavior and actions. These changes can happen very quickly so it is important to be mindful of any sudden differences.
- Be aware of common warning signs that might be a signal for risk of suicide. Some of these are:
 - Talking or thinking about wanting to hurt yourself or end your life
 - Withdrawing from friends and family
 - Becoming depressed or having your depression get worse
 - Becoming preoccupied with death and dying
 - Giving away prized possessions

We again urge patients and families to contact their doctor before stopping an epilepsy medication because this may possibly lead to seizures and worsening of mood.

How can I manage my side effects? Side effects such as dizziness, drowsiness or fatigue may be seen within the first few days of starting the drug, or when the dose of medicine has been increased. These side effects usually go away on their own. To help lessen these side effects:

- Talk to the doctor about starting at a low dose and increasing it slowly.
- Take the first dose in the evening or before bedtime.
- Take the higher dose in the evening or before bedtime when the dose is changed.
- Talk to your doctor about how many times a day to take the medicine. Some people have fewer side effects when they first start the drug if they take it more frequently.

When should I call my doctor?

- Call a doctor right away if side effects become severe or cause problems in your ability to function, or if you have any of the following problems: staggering walk, rash, blood in urine, sudden back pain, or an allergic reaction.
- Do not stop the medicine without talking to your doctor first.

Can this seizure medicine affect bone health? The effect of topiramate on bone health is not fully known. However, a person who has the condition called metabolic acidosis (too much acid in the blood caused by a loss of bicarbonate from the kidneys) can develop thinning of the bones and bone loss if the condition is not treated properly. Regular exercise and diet are very important to help keep strong bones. People should talk to their doctor before taking calcium supplements, because extra calcium could increase the risk of kidney stones in some people who are also taking topiramate. People who have thinning of the bones may also need to take prescription medicines to treat this. Talk to your doctor about tests to check the health of your bones and what to do next.

Can I drink alcohol while on this medicine? People taking this medicine should not drink alcohol, because topiramate can increase the effects of alcohol.

May I drive while taking topiramate? Use caution when driving, operating machinery, or performing other hazardous activities. Topiramate may cause dizziness, fatigue, sleepiness, or other symptoms that may affect your safety, especially in the first couple of weeks. If you have these problems or are having seizures, avoid these activities and talk to your doctor.

Just for Women:

Is this medicine safe to take during pregnancy? Topiramate has an FDA pregnancy category of “C” meaning that the benefits of taking the medicine may outweigh the risks of harming the baby. If you find or suspect that you are pregnant, continue use of this medicine and contact your doctor right away. Talk to your doctor about the potential benefits and risks before making any decisions about use of this medicine. Seizures can be harmful to the mother and the developing baby but these can be lessened with proper care.

Does this medicine affect birth control pills? Contraceptives or birth control that contain the hormones estrogen or progesterone (such as birth control pills, injections, or patches) may not work completely to prevent pregnancy when a woman is also taking topiramate. The dose of contraceptive may need to be increased or injections given more frequently. Talk to your doctor if you start or stop hormonal birth control and for specific instructions on the dose of birth control. Other forms of birth control, such as barrier methods, may also be suggested. Call your doctor if you have any signs of breakthrough bleeding or symptoms of pregnancy.

Will the medicine affect my menstrual cycle? This medicine should not affect the menstrual cycle. If your cycle becomes irregular, call your doctor.

Can I breast feed while taking this medicine? There is limited information on how much topiramate is passed through breast milk. The potential for serious side effects in nursing infants is unknown. According to the American Academy of Neurology, the benefits for the infant and mother are believed to outweigh the risks for adverse effects. Talk to your doctor regarding this option.

Are there any specific vitamins I should be taking? Women who could possibly get pregnant should be taking at least 0.4 milligrams (mg) of folic acid or folate each day. Women taking some seizure medicines may need to take a higher dose of folic acid, up to 4 mg each day. Talk to your health care provider for specific instructions. Folic acid is also found in leafy dark green vegetables, fruits and juices, and lentils.

More Questions?

For more detailed information about topiramate please visit www.epilepsy.com and click on Treatment >> Seizure Medicines (www.epilepsy.com/epilepsy/seizure_medicines.html)