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MEDICATION GUIDE

Topiramate (toe pyre' a mate) Extended-Release Capsules USP

What is the most important information I should know about Topiramate Extended-Release Capsules?

Take Topiramate Extended-release capsules whole. Do not sprinkle topiramate extended-release capsules on food, or break, crush, dissolve, or chew topiramate extended-release capsules before swallowing. If you cannot swallow topiramate extended-release capsules whole, tell your healthcare provider. You may need a different medicine.

Do not drink alcohol within 6 hours prior to and 6 hours after topiramate extended-release capsules administration.

Topiramate extended-release capsules 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 extended-release capsules 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 extended-release capsules 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 topiramate extended-release capsules. If you are pregnant, you should talk to your healthcare provider about whether you have metabolic acidosis.

Like other antiepileptic drugs, topiramate extended-release capsules 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 topiramate extended-release capsules without first talking to a healthcare provider.

- Stopping topiramate extended-release capsules 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 extended-release capsules can harm your unborn baby.

- If you take topiramate extended-release capsules 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 extended-release capsules. If the decision is made to use topiramate extended-release capsules, 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 extended-release capsules.
- Tell your healthcare provider right away if you become pregnant while taking topiramate extended-release capsules. You and your healthcare provider should decide if you will continue to take topiramate extended-release capsules while you are pregnant.
- If you take topiramate extended-release capsules 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 extended-release capsule has caused metabolic acidosis during your pregnancy.

- **Pregnancy Registry:** If you become pregnant while taking topiramate extended-release capsules, 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 extended-release capsules and other antiepileptic drugs during pregnancy.

Topiramate extended-release capsules may decrease the density of bones when used over a long period.

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

What are topiramate extended-release capsules?

Topiramate extended-release capsule is a prescription medicine used:

- to treat certain types of seizures (partial onset seizures and primary generalized tonic-clonic seizures) in people 6 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 6 years and older
- to prevent migraine headaches in adults and adolescents 12 years of age and older.

Who should not take topiramate extended-release capsules?

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

Before taking topiramate extended-release capsules, 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, 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. Topiramate passes into your 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 extended-release capsules.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially, tell your healthcare provider if you take:

- Valproic acid (such as 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 extended-release capsules may make your birth control less effective. Tell your healthcare provider if your menstrual bleeding changes while you are using birth control and topiramate extended-release capsules.

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 extended-release capsules?

- Take topiramate extended-release capsules exactly as prescribed.
- Your healthcare provider may change your dose. **Do not** change your dose without talking to your healthcare provider.
- Take topiramate extended-release capsules whole. **Do not** sprinkle topiramate extended-release capsules on food, or break, crush, dissolve, or chew topiramate extended-release capsules before swallowing.
- Topiramate extended-release capsules 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 extended-release capsules.
- If you take too much topiramate extended-release capsules, call your healthcare provider right away or go to the nearest emergency room.
- Talk to your health care provider on what you should do if you miss a dose.
- Do not stop taking topiramate extended-release capsules without talking to your healthcare provider. Stopping topiramate extended-release capsules suddenly may cause serious problems. If you have epilepsy and you stop taking topiramate extended-release capsules suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking topiramate extended-release capsules slowly.
- Your healthcare provider may do blood tests while you take topiramate extended-release capsules.

What should I avoid while taking topiramate extended-release capsules?

- Do not drink alcohol within 6 hours before or 6 hours after taking topiramate extended-release capsules. Topiramate extended-release capsules and alcohol can cause serious side effects such as severe sleepiness and dizziness and an increase in seizures.
- Do not drive a car or operate heavy machinery until you know how topiramate extended-release capsules affects you. Topiramate extended-release capsules can slow your thinking and motor skills and may affect vision.

What are the possible side effects of topiramate extended-release capsules?

Topiramate extended-release capsules may cause serious side effects, including:

See “What is the most important information I should know about topiramate extended-release capsules?”

- **Effects on thinking and alertness.** Topiramate extended-release capsule may affect how you think, and cause confusion, problems with concentration, attention, memory, or speech. Topiramate extended-release capsule may cause depression or mood problems, tiredness, and sleepiness.
- **Dizziness or loss of muscle coordination.**
- **Severe multiorgan reactions.** Treatment with topiramate extended-release capsule 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 extended-release capsule may cause a severe rash with blisters and peeling skin, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome). Topiramate extended-release capsule 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 extended-release capsule. 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 extended-release capsule 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 extended-release capsule to decrease your chances of getting kidney stones.
 - **Low body temperature.** Taking topiramate extended-release capsule when you are also taking valproic acid can cause a drop in body temperature to less than 95°F, feeling tired, confusion, or coma.

Call your healthcare provider right away if you have any of the symptoms above.

The most common side effects of topiramate extended-release capsules include:

- | | | |
|---|--|--------------------------|
| • tingling of the arms and legs (paresthesia) | • nervousness | • fever |
| • not feeling hungry | • speech problems | • tiredness |
| • nausea | • dizziness | • sleepiness/drowsiness |
| • weight loss | • slow reactions | • difficulty with memory |
| • abnormal vision | • upper respiratory tract infection | • diarrhea |
| • a change in the way foods taste | • decreased feeling or sensitivity, especially on the skin | • pain in abdomen |

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 extended-release capsules.

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 Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How should I store topiramate extended-release capsules?

- Store topiramate extended-release capsules at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep topiramate extended-release capsules in a tightly closed container.
- Keep topiramate extended-release capsules dry and away from moisture and light.
- **Keep topiramate extended-release capsules and all medicines out of the reach of children.**

General information about the safe and effective use of topiramate extended-release capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use topiramate extended-release capsules for a condition for which it was not prescribed. Do not give topiramate extended-release capsules 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 extended-release capsules that is written for health professionals.

What are the ingredients in topiramate extended-release capsules?

Active ingredient: topiramate

Inactive ingredients: docusate sodium, sodium benzoate, ethylcellulose, hypromellose, mannitol, opadry AMB white, sugar spheres, talc, and triethyl citrate

The Opadry AMB White is consists of lecithin (soy), polyvinyl alcohol, talc, titanium dioxide, and xanthan gum

The capsule shells contain gelatin and titanium dioxide.

All capsule shells are imprinted with black print that contains black iron oxide, potassium hydroxide, propylene glycol, and shellac. Additionally, 50 mg capsule body is imprinted with red print that contains FD & C red #40 aluminium lake, povidone, propylene glycol, shellac, sodium hydroxide, and titanium dioxide.

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Manufactured for:

Lupin Pharmaceuticals, Inc.

Naples, FL 34108

United States

MADE IN INDIA

For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

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