Topiramate Tablets, USP

**Inactive ingredients:** colloidal silicon dioxide, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, talc and titanium dioxide.

**Topiramate Capsules, USP**

Active ingredient: topiramate, USP

Inactive ingredients: cellulose acetate, gelatin, hypromellose, povidone, sodium lauryl sulfate, sugar spheres, talc and titanium dioxide.

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This Medication Guide has been approved by the U.S. Food and Drug Administration. This product's label may have been updated. For current full prescribing information, please visit www.zydususa.com

**Medication Guide**

Topiramate (toe-PIR-a-mate) Tablets, USP

**Topiramate (toe-PIR-a-mate) Capsules, USP**

**What is the most important information I should know about Topiramate?**

Topiramate may cause eye problems. Serious eye problems include:

- 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 problems while taking topiramate, including any new problems with your vision.

Topiramate 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. Call your healthcare provider right away if you have a high fever that does not go away, or decreased sweating.

Topiramate 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 worn out
- 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. If you are pregnant, you should talk to your healthcare provider about whether you have metabolic acidosis.

**MEDICATION GUIDE**

Topiramate (toe-PIR-a-mate) Tablets, USP

Topiramate (toe-PIR-a-mate) Capsules, USP

**Like other antiepileptic drugs, topiramate 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 without first talking to a healthcare provider.

- Stopping topiramate 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 suggest you try a different medicine for your seizures.

**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.
- Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- new or worse irritability
- acting aggressive, being angry, or violent
- new or worse anxiety
- new or worse depression
- thoughts about suicide or dying

**Other information**

- Like other antiepileptic drugs, topiramate 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:

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- new or worse depression
- thoughts about suicide or dying
• 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. If the decision is made to use topiramate, 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.

• Tell your healthcare provider right away if you become pregnant while taking topiramate. Your and your healthcare provider should discuss if you will continue to take topiramate while you are pregnant.

• If you take topiramate during pregnancy, your baby may be smaller than expected at birth. Talk to your healthcare provider if you have questions about this risk during pregnancy. If you take topiramate, your baby may be smaller than expected at birth. 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 has caused metabolic acidosis during your pregnancy.

• Pregnancy Registry: If you become pregnant while taking topiramate, 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 topiramate? Topiramate 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.

• to treat certain types of seizures (partial onset seizures and primary generalized tonic-clonic seizures) in adults and children 2 years and older.

• to prevent migraine headaches in adults and adolescents 12 years and older.

What should I tell my healthcare provider before taking topiramate? Before taking topiramate, 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, 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 ever had a stroke.

• have eye problems, especially glaucoma.

• have diabetes.

• have a growth problem.

• are on a diet high in fat and low in carbohydrates, which is called a ketogenic diet.

• are having surgery or are going to become pregnant.

• are breastfeeding.

• are pregnant or will become pregnant.

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

• Topiramate and other medicines may affect each other causing side effects.

• Especially tell your healthcare provider if you take:

  • Valproic acid (such as DEPAKENE® and DEPAKOTE®).

  • any medicines that impair or decrease your thinking, concentration, or memory, or speech. Topiramate can affect each other causing side effects such as sleepiness and dizziness.

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• Do not stop taking topiramate without talking to your healthcare provider. Stopping topiramate suddenly may cause serious problems. If you have epilepsy and you stop taking topiramate suddenly, you may have more seizures. If you have epilepsy and you stop taking topiramate suddenly, you may have more seizures.

• If you miss a single dose of topiramate, 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 topiramate, 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 topiramate without talking to your healthcare provider. Stopping topiramate suddenly may cause serious problems. If you have epilepsy and you stop taking topiramate suddenly, you may have more seizures.

• Your healthcare provider may do blood tests while you take topiramate.

• Do not drink alcohol while taking topiramate. Topiramate 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 topiramate affects you. Topiramate can slow your thinking and motor skills, and affect vision.

What are the possible side effects of topiramate? Topiramate may cause serious side effects including:

• High blood ammonia levels. High ammonia in the blood can affect your mental activities, slow your alertness, make you feel tired, or cause you to stop breathing. Ammonia is made when topiramate is taken with a medicine called valproic acid (DEPAKENE® and DEPAKOTE®).

• Kidney stones. Drink plenty of fluids when taking topiramate to decrease your chances of getting kidney stones. Drink plenty of fluids during the day. This may help prevent kidney stones while taking topiramate.

• Low body temperature. Taking topiramate when you are also taking valproic acid can cause a drop in body temperature to less than 95°F, feeling tired, confusion, or coma.

• Effects on thinking and alertness. Topiramate may affect how you think and cause confusion, problems with concentration, attention, memory, or speech. Topiramate 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 topiramate 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