Important Safety Information

EPRONTIA® (topiramate) oral solution, 25 mg/mL

EPRONTIA is indicated for**:**

- Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older.
- Adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.
- Preventive treatment of migraine in patients 12 years of age and older.

A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. Ask your pharmacist or doctor for assistance in the selection of a dosing device.

Additional Important Safety Information

What is the most important information I should know about EPRONTIA?

EPRONTIA can 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.

EPRONTIA 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 develop a high fever, a fever that does not go away, or decreased sweating.

EPRONTIA 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 experience:

- Feeling tired
- Not feeling hungry (loss of appetite)
- Changes in heartbeat
- 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 EPRONTIA. If you are pregnant, you should talk to your healthcare provider about being monitored for metabolic acidosis.

Like other antiepileptic drugs, EPRONTIA may cause suicidal thoughts or actions. 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
- Panic attacks
- An extreme increase in activity and talking (mania)
- Feeling agitated or restless
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive or being angry or violent
- Acting on dangerous impulses
- Other unusual changes in behavior or mood

Do not stop EPRONTIA without first talking to a healthcare professional.

- Stopping EPRONTIA suddenly, can cause serious problems.
- If you have epilepsy and you stop taking EPRONTIA suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking EPRONTIA slowly.
- If you miss a single dose of EPRONTIA, take it as soon as you can. However, if you are within 6 hours of taking your next scheduled dose, wait to take your usual dose of EPRONTIA 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.

EPRONTIA can harm your unborn baby.

- Tell your healthcare provider right away if you become pregnant while taking EPRONTIA. You and your healthcare provider should decide if you will continue to take EPRONTIA while you are pregnant.

Before taking EPRONTIA, 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 receiving kidney dialysis
- Have a history of metabolic acidosis (i.e., 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 (i.e., a ketogenic diet)
- Are having surgery
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed. EPRONTIA passes into breast milk. Diarrhea and sleepiness have been reported in breastfed infants whose mothers received topiramate treatment. It is not known if the EPRONTIA that passes into breast milk can cause serious harm to your baby. Talk to your healthcare provider about the best way to feed your baby if you take EPRONTIA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. EPRONTIA and other medicines may affect each other, causing side effects. Especially tell your healthcare provider if you take:

- Valproic acid (such as Depakene® or Depakote®).
- Any medicines that impair or decrease your thinking, concentration, or muscle coordination.
- Birth control pills. EPRONTIA 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 EPRONTIA.

How should I take EPRONTIA?

- Take EPRONTIA exactly as prescribed.
- Your healthcare provider may change your dose. **Do not** change your dose without talking to your healthcare provider.
- EPRONTIA can be taken before, during, or after a meal. Drink plenty of fluids during the day. This may help prevent kidney stones while taking EPRONTIA.
- If you take too much EPRONTIA, call your healthcare provider right away or go to the nearest emergency room.
- If you miss a single dose of EPRONTIA, 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 EPRONTIA 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 EPRONTIA without talking to your healthcare provider. Stopping EPRONTIA suddenly may cause serious problems. If you have epilepsy and you stop taking EPRONTIA suddenly, you may have seizures that do not stop. Your healthcareprovider will tell you how to stop taking EPRONTIA slowly.
- Your healthcare provider may do blood tests while you take EPRONTIA.

What should I avoid while taking EPRONTIA?

- You should not drink alcohol while taking EPRONTIA. EPRONTIA and alcohol can affect each other, causing side effects such as sleepiness and dizziness.
- Do not drive a car or operate machinery until you know how EPRONTIA affects you. EPRONTIA can slow your thinking and motor skills and may affect vision.

Even when taking EPRONTIA or other antiepileptic medicines, some people with epilepsy will continue to have unpredictable seizures. Therefore, use caution and talk to your doctor before engaging in any activities where loss of consciousness could result in serious danger to you or thosearound you (including swimming, driving a car, climbing in high places, etc.).

What are the possible side effects of EPRONTIA?

See "*What is the most important information I should know about EPRONTIA?*" above. EPRONTIA 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 vomiting. This has been observed when EPRONTIA is taken with a medicine called valproic acid (Depakene® or Depakote®).
- **Effects on thinking and alertness.** EPRONTIA may affect how you think and cause confusion, and problems with concentration, attention, memory, or speech. EPRONTIA may cause depressionor mood problems, tiredness, and sleepiness.

- **Dizziness or loss of muscle coordination.**
- **Decrease in Bone Mineral Density**. Long-term treatment with EPRONTIA can decrease bone formation and increase bone loss in children.
- **Negative Effects on Growth (Height and Weight).** Long-term EPRONTIA treatment may decrease growth as reflected by slower height increase and weight gain in pediatric patients.
- **Serious skin reactions.** EPRONTIA may cause a severe rash with blisters and peeling skin, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome). EPRONTIA 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.
- **Kidney stones.** Drink plenty of fluids when taking EPRONTIA to decrease your chances of getting kidney stones.
- **Low body temperature.** Taking EPRONTIA when you are also taking valproic acid can cause a drop in body temperature to less than 95°F, feeling tired, confusion, or coma.

The most common side effects of EPRONTIA include:

- Tingling of the arms and legs
- Not feeling hungry
- Nausea
- A change in the way foods taste
- Diarrhea
- Weight loss
- Nervousness
- Upper respiratory tract infections
- Speech problems
- Tiredness
- Dizziness
- Sleepiness/drowsiness
- Slow reactions
- Difficulty with memory
- Pain in the abdomen
- Fever
- Abnormal vision
- Decreased feeling or sensitivity, especially in the skin

These are not all the possible side effects of EPRONTIA.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

The Important Safety Information does not include all the information needed to use EPRONTIA safely and effectively. Visit EPRONTIA.com for full prescribing information.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.
