MEDICATION GUIDE

Trokendi XR™ (tro-KEN-dee eks ahr)

(topiramate)

Extended-release Capsules

Read this Medication Guide before you start taking Trokendi XR™ and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about Trokendi XR™, talk to your healthcare provider or pharmacist.

What is the most important information I should know about Trokendi XR™?

Take Trokendi XR™ capsules whole. Do not sprinkle Trokendi XR™ on food, or break, crush, dissolve, or chew Trokendi XR™ capsules before swallowing. If you cannot swallow Trokendi XR™ 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 Trokendi XR™ administration.

Trokendi XR™ 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.

Trokendi XR™ 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.

Trokendi XR™ 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 Trokendi XR™. If you are pregnant, you should talk to your healthcare provider about whether you have metabolic acidosis.

Like other antiepileptic drugs, Trokendi XR™ 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 Trokendi XR™ without first talking to a healthcare provider.

- Stopping Trokendi XR™ 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.

Trokendi XR™ can harm your unborn baby.

- If you take Trokendi XR™ during pregnancy, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant.
- Cleft lip and cleft palate 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 Trokendi XR™. If the decision is made to use Trokendi XR™, 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 Trokendi XR™.
- Tell your healthcare provider right away if you become pregnant while taking Trokendi XR™. You and your healthcare provider should decide if you will continue to take Trokendi XR™ while you are pregnant.
- Metabolic acidosis may have harmful affects on your baby. Talk to your healthcare provider if Trokendi XR™ has caused metabolic acidosis during your pregnancy.
- Pregnancy Registry: If you become pregnant while taking Trokendi XR™, 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 Trokendi XR™ and other antiepileptic drugs during pregnancy.

What is Trokendi XR™?

Trokendi XR™ is a prescription medicine used:

- to treat certain types of seizures (partial onset seizures and primary generalized tonic-clonic seizures) in people 10 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.

What should I tell my healthcare provider before taking Trokendi XR™?

Before taking Trokendi XR™, tell your healthcare provider about all 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. Trokendi XR™ passes into your breast milk. It is not known if the Trokendi XR™ that passes into breast milk can harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take Trokendi XR™.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Trokendi XR™ and other medicines may affect each other causing side effects.

Especially, tell your healthcare provider if you take:

- Metformin (such as Glucophage)
- Valproic acid (such as DEPAKENE® or DEPAKOTE®)
- any medicines that impair or decrease your thinking, concentration, or muscle coordination
- birth control pills. Trokendi XR™ 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 Trokendi XR™.

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 Trokendi XR™?

- Take Trokendi XR™ exactly as prescribed.
- Your healthcare provider may change your dose. **Do not** change your dose without talking to your healthcare provider.
- Take Trokendi XR™ capsules whole. **Do not** sprinkle Trokendi XR™ on food, or break, crush, dissolve, or chew Trokendi XR™ capsules before swallowing.
- Trokendi XR™ can be taken before, during, or after a meal. Drink plenty of fluids during the day. This may help prevent kidney stones while taking Trokendi XR™.
- If you take too much Trokendi XR™, call your healthcare provider or poison control center right away or go to the nearest emergency room.
- If you miss a single dose of Trokendi XR™, take it as soon as you can. 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 Trokendi XR™ without talking to your healthcare provider.

Stopping Trokendi XR™ suddenly may cause serious problems. If you have epilepsy and you stop taking Trokendi XR™ suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking Trokendi XR™ slowly.

- Your healthcare provider may do blood tests while you take Trokendi XR™.

What should I avoid while taking Trokendi XR™?

- Do not drink alcohol within 6 hours before or 6 hours after taking Trokendi XR™ capsules. Trokendi XR 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 Trokendi XR™ affects you. Trokendi XR™ can slow your thinking and motor skills, and may affect vision.

What are the possible side effects of Trokendi XR™?

Trokendi XR™ may cause serious side effects including:

See "What is the most important information I should know about Trokendi XR™?"

- **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 Trokendi XR™ is taken with a medicine called valproic acid (DEPAKENE ® and DEPAKOTE®).
- **Kidney stones.** Drink plenty of fluids when taking Trokendi XR™ to decrease your chances of getting kidney stones.
- **Low body temperature.** Taking Trokendi XR™ when you are also taking valproic acid cause a drop in body temperature to less than 95ºF, feeling tired, confusion, or coma.
- **Effects on thinking and alertness.** Trokendi XR™ may affect how you think, and cause confusion, problems with concentration, attention, memory, or speech. Trokendi XR™ 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 Trokendi XR™ 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

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 Trokendi XR™. For more information, ask your healthcare provider or pharmacist.

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 Supernus Pharmaceuticals, Inc. at 1-866-398-0833.

How should I store Trokendi XR™?

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

General information about Trokendi XR™

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Trokendi XR™ for a condition for which it was not prescribed. Do not give Trokendi XR™ to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Trokendi XR™. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Trokendi XR™ that is written for health professionals.

For more information, go to www.trokendixrcom or call1-866-398-0833.

What are the ingredients in Trokendi XR™?

Active ingredient: topiramate

Inactive ingredients:

Sugar Spheres, NF, Hypromellose (Type 2910), USP, mannitol, USP, docusate sodium, USP, sodium benzoate, NF,, ethylcellulose, NF, oleic acid, NF, medium chain triglycerides, NF, polyethylene glycol, NF, polyvinyl alcohol, USP titanium dioxide, USP, talc, USP, lecithin, NF, xanthan gum, NF

Capsule shells: Gelatin, USP; titanium Dioxide, USP, and Colorants.

Colorants:

FD&C Blue #1 (all strength capsules)

Yellow iron oxide, USP (25 mg and 50 mg capsules)

FD&C red #3 (50 mg, 100 mg and 200 mg capsules)

FD&C yellow #6 (50 mg, 100 mg and 200 mg capsules)

Riboflavin, USP (25 mg capsules)

All capsule shells are imprinted with black print that contains shellac, NF, and black iron oxide, NF.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by: Catalent Pharma Solutions, Winchester, KY USA 40391

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