

MEDICATION GUIDE
POTIGA® (po-TEE-ga) tablets, CV
(ezogabine)

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

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

Do not stop POTIGA without first talking to a healthcare provider. Stopping POTIGA suddenly can cause serious problems. Stopping POTIGA suddenly can cause you to have more seizures more often.

1. POTIGA can cause changes to your retina, which is located in the back of your eye and is needed for vision. These types of changes can cause vision loss.

- If a decrease in your vision happens, it is not known if it will get better.
- You and your healthcare provider should decide if the benefit of taking POTIGA is more important than the possible risk of vision loss.
- You should have a complete eye exam if you are currently taking POTIGA or before starting treatment, and then every 6 months while taking POTIGA.
- Tell your healthcare provider right away if you notice any changes in your vision.

2. POTIGA can make it hard for you to urinate (empty your bladder) and may cause you to be unable to urinate. Call your healthcare provider right away if you:

- are unable to start urinating.
- have trouble emptying your bladder.
- have a weak urine stream.
- have pain with urination.

3. POTIGA can cause changes in the color of your skin, nails, lips, roof of your mouth, and whites of your eyes or insides of your eyelids.

- The changes in color may be blue, grey-blue, or brown.
- Most changes in color have happened in people who have taken POTIGA for at least 2 years, but may happen earlier.
- It is not known if the changes in color go away after stopping POTIGA.
- Tell your healthcare provider if you notice any changes in color to your body.

4. POTIGA can cause mental (psychiatric) problems, including:

- confusion
- new or worse aggressive behavior, hostility, anger, or irritability
- new or worse psychosis (hearing or seeing things that are not real)
- being suspicious or distrustful (believing things that are not true)
- other unusual or extreme changes in behavior or mood

Tell your healthcare provider right away if you have any new or worsening mental problems while using POTIGA.

5. Like other antiepileptic drugs, POTIGA 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
- attempt 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

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.

What is POTIGA?

POTIGA is a prescription medicine that is used with other medicines to treat partial-onset seizures in adults with epilepsy when several other medicines have not worked well. POTIGA is used when the benefit of taking it is more important than the possible risk of vision loss.

POTIGA is a controlled substance (CV) because it can be abused or lead to drug dependence. Keep your POTIGA in a safe place to protect it from theft. Never give your POTIGA to anyone else because it may harm them. Selling or giving away this medicine is against the law.

It is not known if POTIGA is safe and effective in children under 18 years of age.

What should I tell my healthcare provider before taking POTIGA?

Before you take POTIGA, tell your healthcare provider if you:

- have trouble urinating.
- have an enlarged prostate.
- have or have had depression, mood problems, or suicidal thoughts or behavior.
- have heart problems, including a condition called long QT Syndrome, or have low potassium or magnesium in your blood.
- have liver problems.
- have kidney problems.
- drink alcohol.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if POTIGA will harm your unborn baby.
 - If you become pregnant while taking POTIGA, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. The purpose of this registry is to collect information about the safety of medicines used to treat seizures during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- are breastfeeding or plan to breastfeed. It is not known if POTIGA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take POTIGA. You and your healthcare provider should decide if you will take POTIGA or breastfeed. You should not do both.

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

Taking POTIGA with certain other medicines can affect each other, causing side effects.

Especially tell your healthcare provider if you take:

- phenytoin (DILANTIN[®], PHENYTEK[®])

- carbamazepine (CARBATROL[®], TEGRETOL[®], TEGRETOL[®]-XR, EQUETRO[®], EPITOL[®])

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take POTIGA?

- Take POTIGA exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how much POTIGA to take and when to take it.
- Your healthcare provider may change your dose of POTIGA. Do not change your dose without talking to your healthcare provider.
- POTIGA can be taken with or without food.
- Swallow POTIGA tablets whole. Do not break, crush, dissolve, or chew POTIGA tablets before swallowing.
- If you take too much POTIGA, call your local Poison Control Center or go to the nearest hospital emergency room right away.

What should I avoid while taking POTIGA?

Do not drive, operate machinery, or do other dangerous activities until you know how POTIGA affects you. POTIGA can cause dizziness, sleepiness, double-vision, and blurred vision.

What are the possible side effects of POTIGA?

POTIGA may cause serious side effects, including:

- See “What is the most important information I should know about POTIGA?”
- **Dizziness and sleepiness.** These symptoms can increase when your dose of POTIGA is increased. See “What should I avoid while taking POTIGA?”
- **Changes in your heart rhythm and the electrical activity of your heart.** Your healthcare provider should monitor your heart during treatment if you have a certain type of heart disease or take certain medications.
- Drinking alcohol during treatment with POTIGA may increase the side effects that you get with POTIGA.

The most common side effects of POTIGA include:

- dizziness
- somnolence
- sleepiness
- tiredness

- confusion
- spinning sensation (vertigo)
- tremor
- problems with balance and muscle coordination, including trouble with walking and moving
- blurred or double vision
- trouble concentrating
- memory problems
- weakness

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 POTIGA. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store POTIGA?

- Store POTIGA at room temperature between 68°F and 77°F (20°C and 25°C).
- **Keep POTIGA and all medicines out of the reach of children.**

General information about the safe and effective use of POTIGA.

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

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

For more information, go to www.potiga.com or call 1-877-3POTIGA (1-877-376-8442).

What are the ingredients in POTIGA?

Active ingredient: ezogabine

Inactive ingredients in all strengths: croscarmellose sodium, hypromellose, lecithin, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, talc, titanium dioxide, and xanthan gum

50-mg and 400-mg tablets also contain: carmine

50-mg, 300-mg, and 400-mg tablets also contain: FD&C Blue No 2

200-mg and 300-mg tablets also contain: iron oxide yellow

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

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