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584 Research Triangle Park, NC 27709
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591 **MEDICATION GUIDE**
592 **POTIGA™ (po-TEE-ga) Tablets, CV**
593 **(ezogabine)**
594

595 Read this Medication Guide before you start taking POTIGA and each time you get a refill.
596 There may be new information. This Medication Guide does not take the place of talking to your
597 healthcare provider about your medical condition or treatment. If you have questions about
598 POTIGA, ask your healthcare provider or pharmacist.
599

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

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

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

- 606
- 607 • are unable to start urinating
 - 608 • have trouble emptying your bladder
 - 609 • have a weak urine stream
 - 609 • have pain with urination

610 **2. POTIGA can cause mental (psychiatric) problems, including:**

- 611
- 611 • confusion
 - 612 • new or worse aggressive behavior, hostility, anger, or irritability
 - 613 • new or worse psychosis (hearing or seeing things that are not real)
 - 614 • being suspicious or distrustful (believing things that are not true)
 - 615 • other unusual or extreme changes in behavior or mood

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

618 **3. Like other antiepileptic drugs, POTIGA may cause suicidal thoughts or actions in a**
619 **very small number of people, about 1 in 500.**

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

- 622 • thoughts about suicide or dying
- 623 • attempt to commit suicide
- 624 • new or worse depression
- 625 • new or worse anxiety
- 626 • feeling agitated or restless
- 627 • panic attacks
- 628 • trouble sleeping (insomnia)
- 629 • new or worse irritability
- 630 • acting aggressive, being angry, or violent
- 631 • acting on dangerous impulses
- 632 • an extreme increase in activity and talking (mania)
- 633 • other unusual changes in behavior or mood

634 Suicidal thoughts or actions can be caused by things other than medicines. If you have
635 suicidal thoughts or actions, your healthcare provider may check for other causes.

636

637 **How can I watch for early symptoms of suicidal thoughts and actions?**

- 638 • Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or
639 feelings.
- 640 • Keep all follow-up visits with your healthcare provider as scheduled.

641 Call your healthcare provider between visits as needed, especially if you are worried about
642 symptoms.

643 **Do not stop POTIGA without first talking to a healthcare provider.**

644 Stopping POTIGA suddenly can cause serious problems. Stopping POTIGA suddenly can cause
645 you to have more seizures more often.

646

647 **What is POTIGA?**

648 POTIGA is a prescription medicine that is used with other medicines to treat partial onset
649 seizures in people with epilepsy who are 18 years of age or older.

650 POTIGA is a controlled substance (CV) because it can be abused or lead to drug dependence.

651 Keep your POTIGA in a safe place to protect it from theft. Never give your POTIGA to anyone
652 else because it may harm them. Selling or giving away this medicine is against the law.

653

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

655

656 **What should I tell my healthcare provider before taking POTIGA?**

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

- 658 • have trouble urinating

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

677 **Tell your healthcare provider about all the medicines you take**, including prescription and
678 non-prescription medicines, vitamins, and herbal supplements. Taking POTIGA with certain
679 other medicines can affect each other, causing side effects. **Especially tell your healthcare**
680 **provider if you take:**

- 681 • digoxin (LANOXIN[®])
- 682 • phenytoin (DILANTIN[®], PHENYTEK[®])
- 683 • carbamazepine (CARBATROL[®], TEGRETOL[®], TEGRETOL[®]-XR, EQUETRO[®],
- 684 EPITOL[®])

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

- 687 • Take POTIGA exactly as your healthcare provider tells you to take it. Your healthcare
- 688 provider will tell you how much POTIGA to take and when to take it.
- 689 • Your healthcare provider may change your dose of POTIGA. Do not change your dose
- 690 without talking to your healthcare provider.
- 691 • POTIGA can be taken with or without food.
- 692 • Swallow POTIGA Tablets whole. Do not break, crush, dissolve, or chew POTIGA tablets
- 693 before swallowing.
- 694 • Talk to your doctor about what to do if you miss one or more doses of POTIGA.
- 695 • If you take too much POTIGA, call your local Poison Control Center or go to the nearest
- 696 hospital emergency room right away.

697

698 **What should I avoid while taking POTIGA?**

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

701

702 **What are the possible side effects of POTIGA?**

703 **POTIGA may cause serious side effects, including:**

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

712 The most common side effects of POTIGA include:

- 713 • dizziness
714 • somnolence
715 • sleepiness
716 • tiredness
717 • confusion
718 • spinning sensation (vertigo)
719 • tremor
720 • problems with balance and muscle coordination, including trouble with walking and moving
721 • blurred or double vision
722 • trouble concentrating
723 • memory problems
724 • weakness

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

726 These are not all the possible side effects of POTIGA. Ask your healthcare provider or
727 pharmacist for more information.

728 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-
729 800-FDA-1088.

730

731 **How should I store POTIGA?**

- 732 • Store POTIGA at room temperature at 59°F to 86°F (15°C to 30°C).
733 • **Keep POTIGA and all medicines out of the reach of children.**

734

735 **General information about the safe and effective use of POTIGA.**

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

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

743 For more information, go to www.potiga.com or call 1-888-825-5249.

744

745 **What are the ingredients in POTIGA?**

746 Active ingredient: ezogabine.

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

749 50-mg and 400-mg tablets also contain: carmine.

750 50-mg, 300-mg, and 400-mg tablets also contain: FD&C Blue No 2.

751 200-mg and 300-mg tablets also contain: iron oxide yellow.

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753 POTIGA is a trademark of Valeant Pharmaceuticals North America.

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756 GlaxoSmithKline. The makers of these brands are not affiliated with and do not endorse
757 GlaxoSmithKline or its products.

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

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