

674 Patients should be advised to notify their physicians if they become pregnant or intend to
675 become pregnant during therapy. Patients should be advised to notify their physicians if they
676 intend to breastfeed or are breastfeeding an infant.

677 Patients should be encouraged to enroll in the NAAED Pregnancy Registry if they
678 become pregnant. This registry collects information about the safety of AEDs during pregnancy.
679 To enroll, patients can call the toll-free number 1-888-233-2334 [*see Use in Specific Populations*
680 (8.1)].

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682 POTIGA is a trademark of Valeant Pharmaceuticals North America LLC.

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686 GlaxoSmithKline
687 Research Triangle Park, NC 27709

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693 **MEDICATION GUIDE**
694 **POTIGA™ (po-TEE-ga) Tablets, CV**
695 **(ezogabine)**

696
697 Read this Medication Guide before you start taking POTIGA and each time you get a
698 refill. There may be new information. This Medication Guide does not take the place
699 of talking to your healthcare provider about your medical condition or treatment. If
700 you have questions about POTIGA, ask your healthcare provider or pharmacist.

701
702 **What is the most important information I should know about POTIGA?**

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

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

- 709 • If a decrease in your vision happens, it is not known if it will get better.

- 710 • You and your healthcare provider should decide if the benefit of taking
711 POTIGA is more important than the possible risk of vision loss.
- 712 • You should have a complete eye exam if you are currently taking POTIGA or
713 before starting treatment, and then every 6 months while taking POTIGA.
- 714 • Tell your healthcare provider right away if you notice any changes in your
715 vision.
- 716 **2. POTIGA can make it hard for you to urinate** (empty your bladder) and may
717 cause you to be unable to urinate. Call your healthcare provider right away if
718 you:
- 719 • are unable to start urinating
- 720 • have trouble emptying your bladder
- 721 • have a weak urine stream
- 722 • have pain with urination
- 723 **3. POTIGA can cause changes in the color of your skin, nails, lips, roof of**
724 **your mouth, and whites of your eyes or insides of your eyelids.**
- 725 • The changes in color may be blue, grey-blue, or brown.
- 726 • Most changes in color have happened in people who have taken POTIGA for
727 at least 2 years, but may happen earlier.
- 728 • It is not known if the changes in color go away after stopping POTIGA.
- 729 • Tell your healthcare provider if you notice any changes in color to your body.
- 730 **4. POTIGA can cause mental (psychiatric) problems, including:**
- 731 • confusion
- 732 • new or worse aggressive behavior, hostility, anger, or irritability
- 733 • new or worse psychosis (hearing or seeing things that are not real)
- 734 • being suspicious or distrustful (believing things that are not true)
- 735 • other unusual or extreme changes in behavior or mood
- 736 Tell your healthcare provider right away if you have any new or worsening
737 mental problems while using POTIGA.
- 738 **5. Like other antiepileptic drugs, POTIGA may cause suicidal thoughts or**
739 **actions in a very small number of people, about 1 in 500.**

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

- 742 • thoughts about suicide or dying
- 743 • attempt to commit suicide
- 744 • new or worse depression
- 745 • new or worse anxiety
- 746 • feeling agitated or restless
- 747 • panic attacks
- 748 • trouble sleeping (insomnia)
- 749 • new or worse irritability
- 750 • acting aggressive, being angry, or violent
- 751 • acting on dangerous impulses
- 752 • an extreme increase in activity and talking (mania)
- 753 • other unusual changes in behavior or mood

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

757
758 **How can I watch for early symptoms of suicidal thoughts and actions?**

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

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

764
765 **What is POTIGA?**

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

770 POTIGA is a controlled substance (CV) because it can be abused or lead to drug
771 dependence. Keep your POTIGA in a safe place to protect it from theft. Never give

772 your POTIGA to anyone else because it may harm them. Selling or giving away this
773 medicine is against the law.

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

775

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

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

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

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

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

802 **Especially tell your healthcare provider if you take:**

- 803 • digoxin (LANOXIN®)
- 804 • phenytoin (DILANTIN®, PHENYTEK®)

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

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

809

810 **How should I take POTIGA?**

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

820

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

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

825

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

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

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

836 The most common side effects of POTIGA include:

- 837 • dizziness

- 838 • somnolence
- 839 • sleepiness
- 840 • tiredness
- 841 • confusion
- 842 • spinning sensation (vertigo)
- 843 • tremor
- 844 • problems with balance and muscle coordination, including trouble with walking
- 845 and moving
- 846 • blurred or double vision
- 847 • trouble concentrating
- 848 • memory problems
- 849 • weakness

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

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

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

856

857 **How should I store POTIGA?**

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

860

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

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

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

870 For more information, go to www.potiga.com or call 1-877-3POTIGA (1-877-376-
871 8442).

872

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

874 **Active ingredient:** ezogabine

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

878 50-mg and 400-mg tablets also contain: carmine

879 50-mg, 300-mg, and 400-mg tablets also contain: FD&C Blue No 2

880 200-mg and 300-mg tablets also contain: iron oxide yellow

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882 POTIGA is a trademark of Valeant Pharmaceuticals North America LLC.

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885 trademarks of GlaxoSmithKline. The makers of these brands are not affiliated with
886 and do not endorse GlaxoSmithKline or its products.

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

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898 September 2013

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