

693 **PHARMACIST—DETACH HERE AND GIVE TO PATIENT**

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**MEDICATION GUIDE**

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**HORIZANT®** (*ho-ri' zant*)

697

**(gabapentin enacarbil)**

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**Extended-Release Tablets**

699

700 Read this Medication Guide before you start taking HORIZANT and each time you  
701 get a refill. There may be new information. This information does not take the place  
702 of talking to your healthcare provider about your medical condition or treatment.

703

704 **What is the most important information I should know about HORIZANT?**

705 **HORIZANT can cause serious side effects:**

706 **1. Do not drive after taking your dose of HORIZANT until you know how**  
707 **HORIZANT affects you, including the morning after you take your dose.**

708 **Do not** operate heavy machinery or do other dangerous activities until you  
709 know how HORIZANT affects you. HORIZANT can cause sleepiness, dizziness,  
710 slow thinking, and can affect your coordination. Ask your healthcare provider  
711 when it would be okay to do these activities.

712 **2. HORIZANT may cause suicidal thoughts or actions in a very small**  
713 **number of people, about 1 in 500.**

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

- 716 • thoughts about suicide or dying
- 717 • attempt to commit suicide
- 718 • new or worse depression
- 719 • new or worse anxiety
- 720 • feeling agitated
- 721 • new or worse restlessness
- 722 • panic attacks
- 723 • new or worse trouble sleeping (insomnia)
- 724 • new or worse irritability
- 725 • acting aggressive, being angry, or violent
- 726 • acting on dangerous impulses
- 727 • an extreme increase in activity and talking (mania)
- 728 • other unusual changes in behavior or mood

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

- 730
- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- 731
- Keep all follow-up visits with your healthcare provider as scheduled.
- 732
- Call your healthcare provider between visits as needed, especially if you are
- 733
- worried about symptoms.
- 734

735 **Do not stop HORIZANT without first talking to a healthcare provider.**

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

739 **3. HORIZANT may cause a serious or life-threatening allergic reaction** that  
740 may affect your skin or other parts of your body such as your liver or blood  
741 cells. You may or may not have rash with these types of reactions. Call a  
742 healthcare provider right away if you have any of the following symptoms:

- skin rash
- hives
- fever
- swollen glands that do not go away
- swelling of your lips or tongue
- yellowing of your skin or eyes
- unusual bruising or bleeding
- severe fatigue or weakness
- unexpected, severe muscle pain
- frequent infections

753

754 These symptoms may be the first signs of a serious reaction. A healthcare provider  
755 should examine you to decide if you should continue taking HORIZANT.

756

757 **What is HORIZANT?**

758 HORIZANT is a prescription medicine used to treat adults with:

- moderate-to-severe primary Restless Legs Syndrome (RLS).
- pain from damaged nerves (postherpetic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection).

762 HORIZANT is not for people with RLS who need to sleep during the daytime and  
763 need to stay awake at night.

764 HORIZANT is not the same medicine as gabapentin (for example, NEURONTIN<sup>®</sup> or  
765 GRALISE<sup>®</sup>) and should not be used in its place.

766 It is not known if HORIZANT is safe and effective in children.

767

768 **What should I tell my healthcare provider before taking HORIZANT?**

769 Before taking HORIZANT, tell your healthcare provider if you:

- 770 • have or have had kidney problems or are on hemodialysis.
- 771 • have or have had depression, mood problems, or suicidal thoughts or behavior.
- 772 • have or have had seizures.
- 773 • have a history of drug abuse.
- 774 • have any other medical conditions.
- 775 • are pregnant or plan to become pregnant.
- 776 • It is not known if HORIZANT will harm your unborn baby. Talk to your  
777 healthcare provider if you are pregnant or plan to become pregnant while taking  
778 HORIZANT. You and your healthcare provider will decide if you should take  
779 HORIZANT while you are pregnant.
- 780 • are breastfeeding or plan to breastfeed. Your body turns HORIZANT into another  
781 drug (gabapentin) that passes into your milk. It is not known if this can harm  
782 your baby. You and your healthcare provider should decide if you will take  
783 HORIZANT or breastfeed.
- 784 • drink alcohol.

785

786 **Tell your healthcare provider about all the medicines you take**, including  
787 prescription and non-prescription medicines, vitamins, and herbal supplements.

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

790

791 **How should I take HORIZANT?**

- 792 • Take HORIZANT exactly as your healthcare provider tells you to take it. Your  
793 healthcare provider will tell you how much HORIZANT to take and when to take  
794 it.
- 795 • Take HORIZANT tablets whole. **Do not** cut, crush, or chew your tablet.
- 796 • Take HORIZANT tablets with food.
- 797 • **Do not stop taking HORIZANT without talking to your healthcare**  
798 **provider first.** If you stop taking HORIZANT suddenly, you may develop side  
799 effects.
- 800 • If you forget to take your medicine at the time recommended by your healthcare  
801 provider, just skip the missed dose. Take the next dose at your regular time. **Do**  
802 **not** take 2 doses at one time.
- 803 • If you take too much HORIZANT, call your healthcare provider or go to the  
804 nearest hospital emergency room right away.

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806 **What should I avoid while taking HORIZANT?**

- 807 • Do not take other medicines that make you sleepy or dizzy while taking  
808 HORIZANT without first talking with your healthcare provider. Taking HORIZANT  
809 with medicines that cause sleepiness or dizziness may make your sleepiness or  
810 dizziness worse.
- 811 • Do not take other gabapentin drugs (for example, NEURONTIN or GRALISE)  
812 while you take HORIZANT.
- 813 • Do not consume alcohol when taking HORIZANT.

814

815 **What are the possible side effects of HORIZANT?**

- 816 • See **“What is the most important information I should know about**  
817 **HORIZANT?”**

818 The most common side effects of HORIZANT include:

- 819 • sleepiness  
820 • dizziness  
821 • headache

822 Tell your healthcare provider if you have any side effect that bothers you or that  
823 does not go away.

824 These are not all the possible side effects of HORIZANT. For more information, ask  
825 your healthcare provider or pharmacist.

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

828

829 **How should I store HORIZANT?**

- 830 • Store HORIZANT between 59° and 86°F (15° and 30°C).  
831 • Keep HORIZANT dry and away from moisture.  
832 • Keep HORIZANT tightly closed in the bottle provided to you. Do not remove any  
833 moisture control packs that may come in the bottle.

834 **Keep HORIZANT and all medicines out of the reach of children.**

835

836 **General Information about the safe and effective use of HORIZANT**

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

841 This Medication Guide summarizes the most important information about  
842 HORIZANT. If you would like more information, talk with your healthcare provider.

843 You can ask your healthcare provider or pharmacist for information about  
844 HORIZANT that was written for healthcare professionals.  
845 For more information about HORIZANT, go to [www.gsk.com](http://www.gsk.com) or call 1-888-825-  
846 5249.

847  
848 **What are the ingredients in HORIZANT?**

849 **Active ingredients:** gabapentin enacarbil

850 **Inactive ingredients:** Both the 300 mg and 600 mg tablets contain colloidal  
851 silicon dioxide, dibasic calcium phosphate dihydrate, glyceryl behenate, magnesium  
852 stearate, sodium lauryl sulfate, and talc. The 300 mg tablets also contain red ferric  
853 oxide.

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

857  
858 Manufactured by:  
859 Patheon Inc.  
860 Research Triangle Park, NC 27709  
861

for:



GlaxoSmithKline  
Research Triangle Park, NC 27709

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872 HZT: 6MG