

Important Safety Information for HORIZANT® (gabapentin enacarbil) Extended-Release Tablets (Patient ISI)

INDICATIONS

HORIZANT® (gabapentin enacarbil) is a prescription medicine used to:

- treat adults with moderate to severe primary Restless Legs Syndrome (RLS). HORIZANT is not for people who need to sleep during the daytime and stay awake at night.
- manage pain from damaged nerves (postherpetic neuralgia) that follows healing of shingles (a painful rash that comes after a herpes zoster infection) in adults.

IMPORTANT SAFETY INFORMATION

- **Do not drive after taking your dose of HORIZANT until you know how it affects you, including the morning after you take it.** Do not operate heavy machinery or do other dangerous activities until you know how HORIZANT affects you. HORIZANT can cause sleepiness, dizziness, slow thinking, and can affect your coordination. Ask your healthcare provider when it is okay to do these activities.
- Do not take other medicines that make you sleepy or dizzy while taking HORIZANT without talking to your healthcare provider. Taking HORIZANT with these other medicines may make your sleepiness or dizziness worse.
- **HORIZANT may cause suicidal thoughts or actions in a very small number of people (about 1 in 500). Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:**
 - thoughts or actions about suicide, self-harm, or dying; attempt to commit suicide
 - new or worsening depression or anxiety; or feeling agitated
 - new or worse restlessness or panic attacks
 - new or worse trouble sleeping (insomnia); or irritability
 - acting aggressive, being angry, or violent; acting on dangerous impulses
 - an extreme increase in activity or talking (mania); other unusual changes in mood or behavior
- **Serious breathing problems.** Serious breathing problems can occur when HORIZANT is taken with other medicines that can cause severe sleepiness or decreased awareness, or when it is taken by someone who already has breathing problems. Watch for increased sleepiness or decreased breathing when starting HORIZANT or when the dose is increased. Get help right away if breathing problems occur.
- **Do not stop taking HORIZANT without first talking to your healthcare provider.** Suicidal thoughts or actions can be caused by things other than medicines. If you have these thoughts or actions, your healthcare provider may check for other causes.
- **HORIZANT may cause a serious or life-threatening allergic reaction** that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have a rash with

these types of reactions. Call a 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, or frequent infections. These symptoms may be the first signs of a serious reaction. A healthcare provider should examine you to decide if you should continue taking HORIZANT.

- HORIZANT is not the same medicine as gabapentin [for example, NEURONTIN® (gabapentin) and GRALISE® (gabapentin)]. HORIZANT should not be used in their place. Do not take these or other gabapentin products while taking HORIZANT.
- Before taking HORIZANT, tell your healthcare provider if you:
 - have or have had kidney problems or are on hemodialysis
 - have or have had depression, mood problems, or suicidal thoughts or behavior
 - have or have had seizures
 - have a history of drug abuse
 - have any other medical conditions
 - are pregnant or plan to become pregnant. It is not known if HORIZANT will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant while taking HORIZANT. You and your healthcare provider will decide if you should take HORIZANT while you are pregnant
 - are breastfeeding or plan to breastfeed. Your body turns HORIZANT into another drug (gabapentin) that passes into your milk. It is not known if this can harm your baby. You and your healthcare provider should decide if you will take HORIZANT or breastfeed
 - drink alcohol
- Do not drink alcohol while taking HORIZANT because it may increase the risk of side effects.
- **Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking HORIZANT with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.
- **Do not stop taking HORIZANT without talking to your healthcare provider first.** If you stop taking HORIZANT suddenly, you may develop side effects.
- The most common side effects of HORIZANT include dizziness, sleepiness, and headache. Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of HORIZANT. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report side effects of prescription drugs by contacting Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

For more information, ask your healthcare provider or pharmacist, or consult the full Prescribing Information [Horizant.com].