For the Management of Postherpetic Neuralgia (PHN) in Adults

Tuesday, April 14, 2015

Faculty Information

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Location

Superior Steakhouse
855 Pierremont Road, Suite 120
Shreveport, Louisiana 71106
318.219.4123

Agenda

6:30PM Arrivals and Registration
7:00PM Dinner
7:30PM Presentation

2 Ways to Register! | Registration code: **4719KM129**

317.208.3620

www.HorizantEducation.com

XenoPort policy restricts these programs to specific specialties, the following are excluded and will not be permitted to attend: Child Neurology, Child Psychiatry, Rheumatology, Nephrology, Adolescent Medicine, Pediatric Medicine, Cardiovascular Surgery, Cosmetic Medicine/Surgery, Gynecological Medicine/Surgery, General Surgery, Hospice Palliative Medicine, Radiology, Dentists, Mid-wives, Pediatrics, Orthopedic Medicine/Surgeons, Endocrinology and Oncology.

Program Description

Join your colleagues for this educational presentation focusing on the disease state of postherpetic neuralgia (PHN). We will discuss concerns in managing your adult patients with PHN while examining how a PROdrug providing dose-proportional bioavailability and sustained, predictable absorption may provide relief. We will further discuss the clinical trial designs, efficacy results, and safety profile information related to the use of HORIZANT. The presentation will be followed by a live question and answer session.

Program Objectives

Upon completion of this program, participants should be better able to

- Discuss the diagnosis and medical management of adult patients with PHN
- Explain how HORIZANT utilizes a thoughtfully engineered transported PROdrug technology to support predictable absorption and dose-proportional bioavailability
- Understand the barriers of absorption and why HORIZANT is not interchangeable with other gabapentin products
- Interpret the clinical evidence establishing the efficacy of HORIZANT in adult PHN patients
- Review the clinical safety profile of HORIZANT when discussing tolerability and dosing with appropriate adult PHN patients

INDICATION
HORIZANT® (gabapentin enacarbil) Extended-Release Tablets are indicated for the management of postherpetic neuralgia (PHN) in adults.

CONTRAINDICATION: None.

Please consult Important Safety Information on page 2 and accompanying full Prescribing Information, including Medication Guide.

Horizant®
gabapentin enacarbil
extended-release tablets
600 mg·300 mg

HORIZANT® (gabapentin enacarbil) Extended-Release Tablets

IMPORTANT SAFETY INFORMATION

Effects on Driving
HORIZANT may cause significant driving impairment. Patients should not drive until they have enough experience on HORIZANT to know if it impairs their driving. Patients' ability to assess their driving competence and degree of somnolence caused by HORIZANT can be imperfect.

Somnolence/Sedation and Dizziness
HORIZANT causes somnolence/sedation and dizziness. Patients should not drive or operate other complex machinery until they have enough experience on HORIZANT to know if it impairs their ability to perform these tasks.

Lack of Interchangeability With Gabapentin
HORIZANT is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles. The same dose of HORIZANT results in different plasma concentrations of gabapentin relative to other gabapentin products. The safety and effectiveness of HORIZANT in patients with epilepsy have not been studied.

Suicidal Behavior and Ideation
HORIZANT is a prodrug of gabapentin, an antiepileptic drug (AED). AEDs increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. As a prodrug of gabapentin, HORIZANT also increases this risk. Patients treated with any AED for any indication should be monitored for new or worsening depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Anyone considering prescribing HORIZANT must balance the risk of suicidal thoughts or behavior with the risk of untreated illness.

Patients, caregivers, and families should be informed that HORIZANT increases the risk of suicidal thoughts and behavior and should be advised of the need to be alert for new or worsening signs of and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Drug Reaction With Eosinophilia and Systemic Symptoms (DRESS)/ Multiorgan Hypersensitivity
Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including gabapentin. HORIZANT is a prodrug of gabapentin. Some of these events have been fatal or life threatening. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved.

It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. HORIZANT should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Discontinuation of HORIZANT
In patients with PHN receiving HORIZANT twice daily, the dose should be reduced to once daily for 1 week prior to discontinuation to minimize the potential of withdrawal seizure.

Tumorigenic Potential
In an oral carcinogenicity study, gabapentin enacarbil increased the incidence of pancreatic acinar cell adenoma and carcinoma in male and female rats. The clinical significance of this finding is unknown.

ADVERSE REACTIONS

The most common adverse reactions for patients with PHN taking HORIZANT 1,200 mg and placebo, respectively, were dizziness (17% and 15%), somnolence/ sedation (10% and 8%), headache (10% and 9%), nausea (8% and 5%), and fatigue (6% and 1%).

A daily dose greater than 1,200 mg/day provided no additional benefit, but caused an increase in adverse reactions.

DRUG INTERACTIONS

Gabapentin enacarbil is released faster from HORIZANT Extended-Release tablets in the presence of alcohol. Consumption of alcohol is not recommended when taking HORIZANT.

HORIZANT taken in conjunction with morphine causes increased somnolence/ sedation, dizziness, and nausea.

USE IN SPECIAL POPULATIONS

Pregnancy and Lactation
Based on animal data, HORIZANT may cause fetal harm. There are no adequate and well-controlled studies of HORIZANT in pregnant women. HORIZANT should be used during pregnancy only if potential benefit justifies potential risk to fetus.

HORIZANT is converted to gabapentin, which is secreted into human milk. Discontinue nursing or discontinue HORIZANT, taking into account the importance of HORIZANT to the mother, due to potential for adverse reactions in nursing infants.

Renal Impairment
In patients with PHN who have compromised renal function, HORIZANT should be dosed based upon creatinine clearance (CrCl): 30 to 59 mL/min, a titration dose of 300 mg in AM for 3 days, increase to maintenance dose of 300 mg twice daily at Day 4 and increase to 600 mg twice daily as needed, tapering requirement of reduced current maintenance dose to once daily in AM for 1 week; 15 to 29 mL/min, a titration dose of 300 mg in AM on Day 1 and Day 3, use 300 mg in AM as maintenance therapy and increase to 300 mg twice daily if needed, tapering requirement necessary if taking 300 mg twice daily, reduce to 300 mg once daily in AM for 1 week, if taking 300 mg once daily, no tapering needed; <15 mL/min, no titration dose, 300 mg every other day in AM and increase to 300 mg once daily in AM if needed, no tapering needed; <15 mL/min on hemodialysis, no titration dose, 300 mg following every dialysis and increase to 600 mg following every dialysis if needed, no tapering needed.

01-081

Derived from 01-083, April 2013

XenoPort, Inc. is committed to the principles in the PhRMA Code on Interactions with Healthcare Professionals. As part of our commitment to the PhRMA code, please note that attendance at this program is limited to healthcare professionals, and the inclusion of spouses or other guests is not permitted.

For US medical doctors or other healthcare professionals with an active state license number, the value of the food, beverage, and/or educational item received when attending this program will be disclosed to the federal government and any applicable state governments as a transfer of value from XenoPort. Due to state regulations, food and beverage will not be provided for healthcare professionals licensed in the states of Minnesota and Vermont, and educational items will not be provided to healthcare professionals licensed in Minnesota. In addition, some states prohibit state and government employees from receiving gifts, which may include educational materials and meals. Consult your state regulations and ethics laws to see if such prohibitions apply to you.

This program is sponsored by XenoPort, and continuing medical education (CME) credit is not available.

Avant Healthcare Communications, our contracted third parties, or activity sponsors will not sell or rent your personally identifiable information.

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