PONVORY® Indication Statement & ISI
CONSUMER

INDICATION STATEMENT

WHAT IS PONVORY®?
PONVORY® is a prescription medicine that is used to treat relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
It is not known if PONVORY® is safe and effective in children.

IMPORTANT SAFETY INFORMATION

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT PONVORY®?

PONVORY® may cause serious side effects, including:

- **Infections** - PONVORY® can increase your risk of serious infections that can be lifethreatening and cause death. PONVORY® lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 1 to 2 weeks of stopping treatment. Your healthcare provider should review a recent blood test of your white blood cells before you start taking PONVORY®. Call your healthcare provider right away if you have any of these symptoms of an infection during treatment and for 1 to 2 weeks after your last dose of PONVORY®:
  - fever
  - tiredness
  - body aches
  - chills
  - nausea
  - vomiting
  - headache with fever, neck stiffness, sensitivity to light, nausea, or confusion
    (these may be symptoms of meningitis, an infection of the lining around your brain and spine)

  Your healthcare provider may delay starting or may stop your PONVORY® treatment if you have an infection.

- **Slow heart rate (bradycardia or bradyarrhythmia) when you start taking PONVORY®. PONVORY®** can cause your heart rate to slow down, especially after you take your first dose. You should have a test to check the electrical activity of your heart called an electrocardiogram (ECG) before you take your first dose.

Only Start your treatment with PONVORY® using the Starter Pack. You must use the PONVORY® Starter Pack by slowly increasing the dose over a 14-day period to help reduce the effect of slowing of your heart rate. It is important to follow the recommended dosing instructions.
Call your healthcare provider if you experience the following symptoms of slow heart rate:

- Dizziness
- Lightheadedness
- Feeling like your heart is beating slowly or skipping beats
- Shortness of breath
- Confusion
- Chest pain
- Tiredness

Do not take PONVORY® if you:

- Have had a heart attack, chest pain called unstable angina, stroke or ministroke (transient ischemic attack or TIA), or certain types of heart failure in the last 6 months.
- Have certain types of heart block or irregular or abnormal heartbeat (arrhythmia) unless you have a pacemaker.
  Talk to your healthcare provider if you have any of these conditions, or do not know if you have any of these conditions.

Before you take PONVORY®, tell your healthcare provider about all your medical conditions, including if you:

- Have a fever or infection, or you are unable to fight infections due to a disease or taking medicines that lower your immune system.
- Have had chicken pox or have received the vaccine for chicken pox. Your healthcare provider may do a blood test for chicken pox virus. You may need to get the full course of vaccine for chicken pox and then wait 1 month before you start taking PONVORY®.
- Have slow heart rate.
- Have an irregular or abnormal heartbeat (arrhythmia).
- Have a history of stroke.
- Have heart problems, including a heart attack or chest pain.
- Have high blood pressure.
- Have breathing problems, including during your sleep (sleep apnea).
- Have liver problems.
- Had or now have a type of skin cancer called basal cell carcinoma (BCC), melanoma, or squamous cell carcinoma
- Have eye problems, especially an inflammation of the eye called uveitis.
- Have diabetes.
- Are pregnant or plan to become pregnant. PONVORY® may harm your unborn baby. Talk with your healthcare provider if you are pregnant or plan to become pregnant. If you are a woman who can become pregnant, you should use effective birth control during your treatment with PONVORY® and for 1 week after you stop taking PONVORY®. Talk to your healthcare provider about what method of birth control is right for you during this time. Tell your healthcare provider right away if you do become pregnant while taking PONVORY® or within 1 week after you stop taking PONVORY®.
- Are breastfeeding or plan to breastfeed. It is not known if PONVORY® passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take PONVORY®.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.
Using PONVORY® and other medicines together may affect each other causing serious side effects.
Especially tell your healthcare provider if you take or have taken: Medicines to control your heart rhythm (antiarrhythmics), or blood pressure (antihypertensives), or heart-beat (such as calcium channel blockers or beta-blockers); medicines that affect your immune system, such as alemtuzumab; and medicines such as rifampin, phenytoin, or carbamazepine.
You should not receive live vaccines during treatment with PONVORY®, for at least 1 month before taking PONVORY®, and for 1 to 2 weeks after you stop taking PONVORY®. If you receive a live vaccine, you may get the infection the vaccine was meant to prevent. Vaccines may not work as well when given during treatment with PONVORY®.
Talk with your healthcare provider if you are not sure if you take any of these medicines.

HOW SHOULD I TAKE PONVORY®?

- Take PONVORY® exactly as your healthcare provider tells you to take it.
- Take PONVORY® 1 time each day.
- Swallow PONVORY® tablets whole.
- Take PONVORY® with or without food.
- Do not stop taking PONVORY® without talking with your healthcare provider first.
- Do not skip a dose.
- Start taking PONVORY® with a 14-day starter pack.
- If you miss taking 1, 2, or 3 tablets in a row of PONVORY® in the 14-day starter pack, continue treatment by taking the first dose you missed. Take 1 tablet as soon as you remember. Then, take 1 tablet a day to continue with the starter pack dose as planned.
- If you miss taking 1, 2, or 3 tablets in a row of PONVORY® while taking the 20 mg maintenance dose, continue treatment with the 20 mg maintenance dose.

• If you miss taking 4 or more tablets in a row of PONVORY®, while taking the 14-day starter pack or the 20 mg maintenance dose, you need to restart treatment with a new 14-day starter pack. Call your healthcare provider if you miss 4 or more doses of PONVORY®. Do not restart PONVORY® after stopping it for 4 or more days in a row without talking to your healthcare provider. If you have certain heart conditions, you may need to be monitored by your healthcare provider for at least 4 hours when you take your next dose.

What are the possible side effects of PONVORY®?
PONVORY® may cause serious side effects, including:
• Breathing problems. Some people who take PONVORY® have shortness of breath. Call your healthcare provider right away if you have new or worsening breathing problems.
• **Liver problems.** PONVORY® may cause liver problems. Your healthcare provider should do blood tests to check your liver before you start taking PONVORY®. Call your healthcare provider right away if you have any of the following symptoms of liver problems:
  • unexplained nausea
  • vomiting
  • stomach (abdominal) pain
  • tiredness
  • loss of appetite
  • yellowing of the whites of your eyes or skin
  • dark urine
• **Increased blood pressure.** Your healthcare provider should check your blood pressure during treatment.
• **Types of skin cancer called basal cell carcinoma (BCC), melanoma, and squamous cell carcinoma.** Certain types of skin cancer have happened with drugs in the same class. Tell your healthcare provider if you have any changes in the appearance of your skin, including changes in a mole, a new darkened area on your skin, a sore that does not heal, or growths on your skin, such as a bump that may be shiny, pearly white, skin-colored, or pink. Your doctor should check your skin for any changes during treatment with PONVORY®. Limit the amount of time you spend in sunlight and ultraviolet (UV) light. Wear protective clothing and use a sunscreen with a high sun protection factor.
• **A problem with your vision called macular edema.** Tell your healthcare provider about any changes in your vision. Your healthcare provider should test your vision before you start taking PONVORY® and any time you notice vision changes during treatment with PONVORY®. Your risk of macular edema is higher if you have diabetes or have had an inflammation of your eye called uveitis.
  Call your healthcare provider right away if you have any of the following symptoms:
  • Blurriness or shadows in the center of your vision
  • A blind spot in the center of your vision
  • Sensitivity to light
  • Unusually colored (tinted) vision

• **Swelling and narrowing of the blood vessels in your brain.** A condition called Posterior Reversible Encephalopathy Syndrome (PRES) has happened with drugs in the same class. Symptoms of PRES usually get better when you stop taking PONVORY®. However, if left untreated, it may lead to a stroke. Call your healthcare provider right away if you have any of the following symptoms:
  • Sudden severe headache
  • Sudden confusion
  • Sudden loss of vision or other changes in vision

• **Severe worsening of multiple sclerosis (MS) after stopping PONVORY®.**
  When PONVORY® is stopped, symptoms of MS may return and become worse compared to before or during treatment. Always talk to your healthcare provider before you stop taking PONVORY® for any reason. Tell your healthcare provider if you have worsening symptoms of MS after stopping PONVORY®.

The most common side effects of PONVORY® include:
• Upper respiratory tract infections
• Elevated liver enzymes (abnormal liver tests)
• High blood pressure (hypertension)
These are not all the possible side effects of PONVORY®. For more information, ask your healthcare provider or pharmacist. See “What is the most important information I should know about PONVORY®?”

Tell your doctor if you have any side effect that bothers you or that does not go away.
Call your doctor for medical advice about side effects. You are also encouraged to report side effects to the FDA: visit http://www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Vanda Pharmaceuticals, Inc., at 1-833-933-9331.

Please see Prescribing Information and Medication Guide.

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