

3 STEPS TO YOUR FIRST DOSE

A GUIDE TO GETTING STARTED ON PONVORY®



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.



Step 1

GET READY

LEARN ABOUT THE TEAM AROUND YOU AND YOUR JOURNEY AHEAD

As you balance your life with relapsing multiple sclerosis (MS), you can reach out to your family, friends, healthcare professional, and others to help navigate and support you in your treatment journey.

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 life-threatening 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.



THE TEAM AROUND YOU

YOU

You know yourself best and play an active role in your care. Family and friends

Healthcare professional

Specialty pharmacy

- Family and friends: Family and friends are there to partner with you to achieve your goals.
- Healthcare professional: Building a partnership with your healthcare professional can help you fully engage in managing your relapsing MS.
- Specialty pharmacy: A specialty pharmacy can ship your prescribed medication to your home and may offer additional support services.

IMPORTANT SAFETY INFORMATION (continued)

Your healthcare provider should review a recent blood test of your white blood cells before you start taking PONVORY®.

A GLANCE AT THE PONVORY® TREATMENT JOURNEY

We know starting treatment is a big step, so we wanted to break it down for you with key milestones.



COMPLETE PRETESTS

Your journey will start with some tests before beginning PONVORY®.

(Learn more in the next section of this brochure.)



BEGIN YOUR 14-DAY STARTER PACK

The Starter Pack begins with a low dose of PONVORY® that gradually increases over 14 days until you are ready to begin your maintenance dose.



START YOUR MAINTENANCE DOSE

After you finish your Starter Pack, you will begin taking your maintenance dose of 20 mg of PONVORY®.

IMPORTANT SAFETY INFORMATION (continued)

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)





lot an actual patient.

Step 2

GET SET

PREPARE TO START TREATMENT WITH PONVORY®

Before you can start PONVORY® safely, your healthcare professional may ask you to complete a few tests:



Electrocardiogram (ECG)



Blood work



Eye exam

Depending on your pretests and/or cardiac history, you might also be asked to complete first dose monitoring. Your healthcare professional will inform you if this monitoring is required.

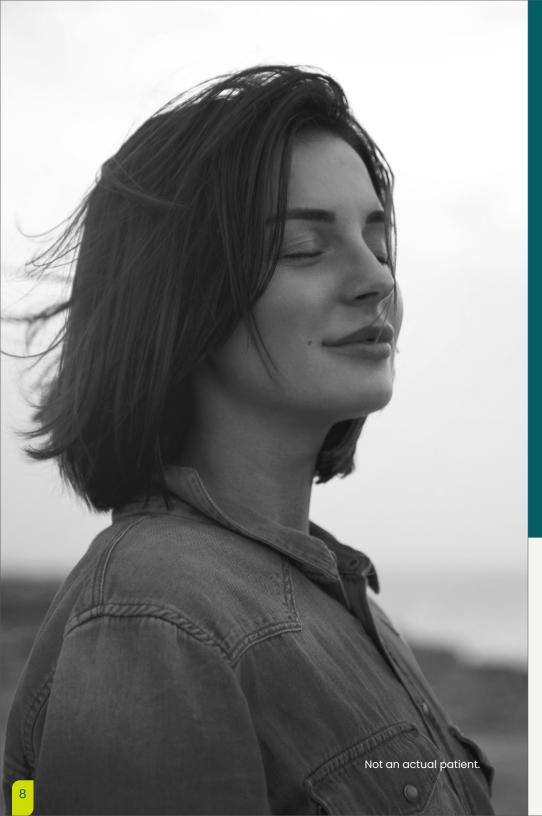
IMPORTANT SAFETY INFORMATION (continued)

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.





Step 3

GO

GET STARTED ON TREATMENT

Get the help you may need when you start PONVORY®. Information on your medicine, education about treatment, and support resources are available to you at ponvoryus.com.

IMPORTANT SAFETY INFORMATION (continued)

Call your healthcare provider if you experience the following symptoms of slow heart rate:

dizziness

• shortness of breath

lightheadedness

- confusion
- feeling like your heart is beating chest pain
- slowly or skipping beats
- tiredness



GETTING YOUR PONVORY® 14-DAY STARTER PACK AND MAINTENANCE DOSE

- After completing your pretests, you and your healthcare professional will determine when you're ready to begin therapy.
- The 14-Day Starter Pack is used for patients beginning treatment with PONVORY®. You will start treatment with a low dose of medication and gradually increase the dose over 14 days, carefully following the instructions in the Starter Pack. After you finish taking the pills in the 14-Day Starter Pack, you will continue treatment using the 20 mg maintenance dose of PONVORY® that will be provided in a separate prescription bottle.
- When you are finishing your 20 mg maintenance dose of PONVORY®, you can work with your specialty pharmacy to help fulfill future shipments of your medication.

For more information about the dosing and administration of PONVORY®, please refer to the <u>Prescribing Information</u> and <u>Medication Guide</u>.



IMPORTANT SAFETY INFORMATION (continued)

Do not take PONVORY® if you:

- have had a heart attack, chest pain called unstable angina, stroke or mini-stroke (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®.





GET A SAVINGS PROGRAM CARD

Enroll and get a Savings Program Card Mobile enrollment available

Use Express Enrollment at MyVandaCarePath.com/ express from a mobile or online device. Once enrolled, receive an electronic Savings Program card that can be saved to your digital wallet on your iPhone or Android device.

IMPORTANT SAFETY INFORMATION (continued)

- 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



IMPORTANT SAFETY INFORMATION (CONTINUED)

- · 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 I 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 I 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



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IMPORTANT SAFETY INFORMATION (CONTINUED)

- **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
- · sensitivity to light
- unusually colored (tinted) vision
- a blind spot in the center of your 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
- seizure

• 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.





VISIT <u>PONVORYUS.COM</u> FOR MORE INFORMATION



Please see Important Safety Information throughout and the full <u>Prescribing Information</u> and <u>Medication Guide</u>.

