Ponvory® (ponesimod) once-daily tablets

A HELPFUL GUIDE TO PONVORY®

A ONCE-DAILY PILL FOR PEOPLE LIVING WITH RELAPSING MS

MS = multiple sclerosis.

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 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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

READY FOR THE UNEXPECTED

Relapsing MS is unpredictable, and your health considerations may change over time. An **agile treatment plan** can help your healthcare team adapt to your needs.

With PONVORY®, your healthcare professional can be ready to help manage certain unexpected events you may face along your MS journey, including **relapses and lesions** or needing to pause therapy for **vaccines, infections, or family planning**.

PROVEN RESULTS

Superior efficacy at reducing relapses* and the number of new or enlarging lesions*

No disability progression for ~90% of people, as measured by time to 3-month CDP†

Over 10 years of data across multiple studies show PONVORY® has a proven safety profile and is generally well-tolerated‡

CDP = confirmed disability progression.
*In a phase 3 study vs Aubagio® lasting ~2 years, PONVORY® was shown to reduce the average number of relapses per year and the average number of new gadolinium-enhancing (GdE) T1 and new or enlarging T2 lesions.
† There was no statistically significant difference between treatment groups.
‡ Includes the phase 3 study, the phase 2, 6-month, placebo-controlled study, and the uncontrolled extension studies.

IMPORTANT SAFETY INFORMATION (continued)

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

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.


Not an actual patient.

AN AGILE TREATMENT PLAN

With your healthcare professional's guidance, PONVORY® can be paused, if needed, and then restarted.§

Immune cells (lymphocytes) may return to normal levels 1 to 2 weeks after pausing,¶ which may be important when planning for certain vaccines or addressing infections

For those thinking about planning for a family,# PONVORY® leaves the body naturally in ~7 days after pausing‖

Always talk to your healthcare professional before pausing PONVORY® for any reason.

§If PONVORY® is paused for 4 or more days in a row, treatment must be restarted with a new 14-Day Starter Pack.
¶In the phase 3 study, lymphocyte counts returned to normal range within 2 weeks after stopping PONVORY®.
#PONVORY® should not be taken during pregnancy. Tell your healthcare professional right away if you become pregnant or plan on becoming pregnant.
‖No elimination procedure required.

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READY FOR WHAT'S NEXT™

PROVEN RESULTS WITH PONVORY®

PONVORY® WAS PROVEN TO HELP CONTROL THE SYMPTOMS AND SIGNS OF RELAPSING MS

About 1130 people participated in the ~2-year study that compared PONVORY® with Aubagio®. The clinical study showed:

PONVORY® was SUPERIOR at reducing relapses and the number of new or enlarging lesions vs a proven oral therapy (Aubagio®)*

PONVORY® stopped 3-month disability progression in ~90% of people. There was no statistically significant difference in the percentages of people experiencing disability progression between PONVORY® and Aubagio®

*PONVORY® reduced the average number of new GdE T1 and new or enlarging T2 lesions.

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)

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

YOUR DAILY PONVORY® JOURNEY

PONVORY® is an oral, once-daily pill that can be taken anywhere. Most people can take their first dose at home†

Unlike injections or infusions, no refrigeration, special storage, or trips to infusion centers are required

Can be taken with or without food and has no known food restrictions

No known drug interactions with selective serotonin reuptake inhibitors (SSRIs), the most commonly prescribed class of antidepressants

† First dose, 4-hour monitoring is required for people with certain cardiac conditions (slow heart rate, certain types of heart block, and heart attack or heart failure occurring >6 months prior to treatment initiation and in stable condition). Supervision of this first dose should take place in a healthcare setting.

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READY FOR WHAT'S NEXT™

RELAPSES

PONVORY® HELPED REDUCE THE AVERAGE NUMBER OF RELAPSES PER YEAR BY 30.5% VS A PROVEN ORAL THERAPY (AUBAGIO®)*

30.5%

FEWER RELAPSES

THAN THOSE TAKING A PROVEN ORAL THERAPY (AUBAGIO®) OVER ABOUT 2 YEARS

Relapses, also known as flare-ups, attacks, or exacerbations, occur when old MS symptoms get worse or new MS symptoms emerge. Some relapses produce 1 symptom, while others can cause 2 or more symptoms at the same time. These symptoms are different for everyone and can range from mild to severe.

*The average relapse rate per year was 0.202 for people taking PONVORY® (567 people) and 0.290 for people taking Aubagio® (566 people) over the course of the clinical study.


Not an actual patient.

IMPORTANT SAFETY INFORMATION (continued)

- **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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

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READY FOR WHAT'S NEXT™

IMPORTANT SAFETY INFORMATION (continued)

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:

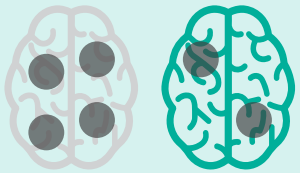
- dizziness
- lightheadedness
- feeling like your heart is beating slowly or skipping beats
- shortness of breath
- confusion
- chest pain
- tiredness

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

LESIONS

PONVORY® WAS PROVEN TO REDUCE THE NUMBER OF NEW GDE T1 LESIONS* AND NEW OR ENLARGING T2 LESIONS† VS A PROVEN ORAL THERAPY (AUBAGIO®)

59% FEWER NEW GdE T1 BRAIN LESIONS



Over the course of the clinical study, people taking PONVORY® experienced an average of 0.18 GdE T1 lesions per magnetic resonance imaging (MRI) vs an average of 0.43 for people taking Aubagio®.

56% FEWER NEW OR ENLARGING T2 BRAIN LESIONS

Over the course of the clinical study, people taking PONVORY® experienced an average of 1.4 new or enlarging T2 lesions per year vs an average of 3.16 for people taking Aubagio®.

For illustrative purposes only. Lesions can be found in any part of the central nervous system, not just those shown.

GdE = gadolinium-enhancing.

*Gadolinium is a contrast agent used in MRI scans that helps detect areas of new inflammation. T1 weighted imaging with gadolinium may show bright areas called enhancing lesions that indicate areas of active inflammation. The number of new GdE T1 lesions was measured by MRI at specific times in the study.

†T2 weighted MRI scans show overall disease burden or lesion load (the total number of lesions, both old and new). The number of new or enlarging T2 lesions (without double counting of lesions) was measured by MRI at specific times in the study.

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READY FOR WHAT'S NEXT™

DISABILITY

FOR MOST PEOPLE, DISABILITY SYMPTOMS DIDN'T WORSEN WITH PONVORY® OR AUBAGIO®*

~90%

of people **didn't have a worsening of disability symptoms** in the clinical study that lasted about 2 years†

3-month CDP showed 89% of people taking PONVORY® vs 87% of people taking Aubagio® didn't have a worsening of disability after 2 years.‡

The disability symptoms that were measured included:
- Neurological function
- Mobility
- The degree of daily walking activity
- The amount of assistance needed to perform routine tasks

*Over the course of the study, disability progression was similar in people taking PONVORY® and people taking Aubagio®. There was no statistically significant difference between the PONVORY® and Aubagio® groups.
†Disability progression was determined with predefined increases in Expanded Disability Status Scale (EDSS) scores, which were confirmed after 3 months over the course of the ~2-year study.
‡3-month disability progression was observed in 10.8% of people taking PONVORY® vs 13.2% taking Aubagio®.


Not an actual patient.

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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

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SAFETY AND SIDE EFFECTS

It's important to know the side effects of any medicine you may start taking. The safety and side effects of PONVORY® were evaluated in 565 people during the ~2-year study.

MOST COMMON SIDE EFFECTS

- Upper respiratory tract infections (PONVORY® 37% vs Aubagio® 34%)
- Elevated liver enzymes (abnormal liver tests) (PONVORY® 23% vs Aubagio® 12%)
- High blood pressure (PONVORY® 10% vs Aubagio® 9%)

OTHER POTENTIAL SERIOUS SIDE EFFECTS

- Infections
- Slow heart rate
- Breathing problems

These aren't all of the potential side effects of PONVORY®. For more information, see the Prescribing Information and Medication Guide or ask your doctor or pharmacist. Tell your doctor if you have any side effects that bother you or that don't go away.


Not an actual patient.

OVER 10 YEARS

Over 10 years of data across multiple studies show PONVORY® has a proven safety profile and is generally well-tolerated*

*Includes the phase 3 study, the phase 2, 6-month, placebo-controlled study, and the uncontrolled extension studies.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

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Not an actual patient.

IMPORTANT SAFETY INFORMATION (continued)

- 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).

AN AGILE TREATMENT PLAN WITH PONVORY®

An agile treatment plan helps your healthcare professional navigate and react to changes in your MS journey. With your healthcare professional's guidance, PONVORY® can be paused, if needed, and then restarted.*

MANAGING VACCINES AND INFECTIONS

PONVORY® locks away immune cells (lymphocytes) without destroying them.†

If your healthcare professional decides it's necessary to pause treatment with PONVORY®, lymphocytes may return to normal levels 1 to 2 weeks after pausing.‡

This might be important when planning for certain vaccines or addressing infections.

*If PONVORY® is paused for 4 or more days in a row, treatment must be restarted with a new 14-Day Starter Pack.
†The exact way PONVORY® works in MS is unknown, but it is believed to work by reducing the number of lymphocytes in the blood.
‡In the phase 3 study, lymphocyte counts returned to normal range within 2 weeks after stopping PONVORY®.

IMPORTANT SAFETY INFORMATION (continued)

- 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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

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AN AGILE TREATMENT PLAN WITH PONVORY®

FAMILY PLANNING

If you're thinking about planning for a family,* PONVORY® leaves the body naturally in ~7 days after pausing.†

PONVORY® may harm your unborn baby. Tell your healthcare professional right away if you become pregnant while taking PONVORY® or within 1 week after you stop taking PONVORY®.

If you're a woman who can become pregnant, you should use effective birth control during your treatment with PONVORY® and for 1 week after you stopped taking PONVORY®. Talk to your healthcare professional about what method of birth control is right for you.

When PONVORY® is stopped, symptoms of MS may return and become worse compared with before or during treatment. Always talk to your healthcare professional before you stop taking PONVORY® for any reason. Tell your healthcare professional if you have worsening symptoms of MS after stopping PONVORY®.

Make sure to discuss family planning or other treatment goals with your healthcare professional. Do not stop taking PONVORY® without talking with your healthcare professional first.

*PONVORY® should not be taken during pregnancy. Tell your healthcare professional right away if you become pregnant or plan on becoming pregnant.
†No elimination procedure required.


Not an actual patient.

IMPORTANT SAFETY INFORMATION (continued)

- 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®.

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READY FOR WHAT'S NEXT™

TALK TO YOUR HEALTHCARE PROFESSIONAL TO SEE IF PONVORY® MAY BE RIGHT FOR YOU

When deciding on a treatment for relapsing MS, you may want to discuss the following with your healthcare professional:

- How you like to take your medicine and how often you like to take it
- How your MS impacts your body and what's most important for you to manage
- Your short- and long-term goals and plans for the future
- How your MS and MS symptoms affect your daily life
- How certain events like vaccines, infections, or planning for a family may impact your MS treatment
- Potential risks and benefits of PONVORY®

IMPORTANT SAFETY INFORMATION (continued)

- 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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

ONCE YOU AND YOUR HEALTHCARE PROFESSIONAL DECIDE ON PONVORY®, YOU SHOULD ALSO DISCUSS THE FOLLOWING:

- All medical problems or preexisting medical conditions, including if you are pregnant or plan on becoming pregnant
- All medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements
- Any vaccines you have received or plan on receiving

GETTING STARTED ON PONVORY®

If you and your healthcare professional choose PONVORY® to treat your relapsing MS, here's what you can expect:

STEP 1. GET READY: LEARN ABOUT THE TEAM AROUND YOU AND YOUR JOURNEY AHEAD

As you balance your life with MS, you can reach out to your family, friends, healthcare professional, and others for support as you navigate your treatment journey.

Learn more about potential savings assistance available to you at ponvory.com.

IMPORTANT SAFETY INFORMATION (continued)

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.


Not an actual patient.

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GETTING STARTED ON PONVORY®


Not an actual patient.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

STEP 2. GET SET: PREPARE TO START PONVORY®

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

- An **electrocardiogram**, or **ECG**, to measure how your heart is working
- **Blood work** to test your overall health, liver function, and antibodies to varicella-zoster virus
- An **eye exam** to determine your risk for developing issues with vision, like macular edema

Most people can take their first dose of PONVORY® at home instead of in a doctor's office or another healthcare setting

Depending on your pretests and/or cardiac history, you might also be asked to complete first dose, 4-hour monitoring, which is required for people with certain cardiac conditions (slow heart rate, certain types of heart block, and heart attack or heart failure occurring >6 months prior to treatment initiation and in stable condition). Your healthcare professional will inform you if this monitoring is required.

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READY FOR WHAT'S NEXT™

GETTING STARTED ON PONVORY®

STEP 3. GO: GET STARTED ON TREATMENT

After completing your pretests, you and your healthcare professional will determine when you're ready to begin PONVORY®. You'll start treatment using a **14-Day Starter Pack** that gradually increases your PONVORY® dose. The Starter Pack is conveniently labeled by day and helps direct you to which dose is next.

After completing the Starter Pack, you will begin taking the **20 mg maintenance dose** of PONVORY®. You can work with your specialty pharmacy to help fulfill future shipments of your medication.

To help you remember to take your pill each day, try combining the habit with something you already do every day, like brushing your teeth, putting on pajamas, or even walking your dog.

IMPORTANT SAFETY INFORMATION (continued)

- 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.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

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READY FOR WHAT'S NEXT™

GET A SAVINGS PROGRAM CARD

ENROLL AND GET A SAVINGS PROGRAM CARD
MOBILE ENROLLMENT AVAILABLE

Use Express Enrollment at MyJanssenCarePath.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)

- 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®.

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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
  - 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 Janssen Pharmaceuticals, Inc., at 1-800-JANSSEN (1-800-526-7736).

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Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

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READY FOR WHAT'S NEXT™

Not actual patients.

FIND OUT WHAT PONVORY® CAN DO FOR YOU

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Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.

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