

**Clean Patient Information Leaflet**

Submission date: 10 February 2023

Reference number: RA/2022/12/249pn

Submission type: Response to Clinical Queries Round 1 (eCTD)

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

Schedule 4

**PONVORY 2 mg film-coated tablets**  
**PONVORY 3 mg film-coated tablets**  
**PONVORY 4 mg film-coated tablets**  
**PONVORY 5 mg film-coated tablets**  
**PONVORY 6 mg film-coated tablets**  
**PONVORY 7 mg film-coated tablets**  
**PONVORY 8 mg film-coated tablets**  
**PONVORY 9 mg film-coated tablets**  
**PONVORY 10 mg film-coated tablets**  
**PONVORY 20 mg film-coated tablets**

Ponesimod

Contains sugar (lactose)

### Read all of this leaflet carefully before you start taking PONVORY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PONVORY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

1. What PONVORY is and what it is used for
2. What you need to know before you use PONVORY
3. How to use PONVORY

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4. Possible side effects
5. How to store PONVORY
6. Contents of the pack and other information

**1. What PONVORY is and what it is used for**

**What PONVORY is**

PONVORY contains the active substance ponesimod.

**What PONVORY is used for**

PONVORY is used to treat adults with 'Relapsing forms of Multiple Sclerosis' (RMS) with active disease.

**What is multiple sclerosis**

Multiple Sclerosis (MS) affects the nerves in the brain and spinal cord (the 'central nervous system').

- In MS, the body's defence system (immune system) does not work properly.
- The immune system attacks a protective layer around nerve cells (called myelin sheath) – this causes inflammation.
- This breakdown of the myelin sheath properly (called demyelination) stops the nerves from working properly.

Symptoms of MS depend on which part of the brain and spinal cord are affected.

This can include problems with walking and balance, weakness, numbness, double vision and blurring, poor coordination, and bladder problems.

Symptoms of a relapse may disappear completely when the relapse is over – but some problems may remain.

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**How PONVORY works**

PONVORY works by reducing the number of circulating lymphocytes (a type of white blood cell).

- It does this by keeping them in the lymphoid organs (lymph nodes).
- This means fewer lymphocytes are available to attack the protective layer around the nerve in the brain and spinal cord.

This decreases the nerve damage caused by MS which:

- reduces the number of attacks (relapses) and,
- slows down the disease from getting worse.

**2. What you need to know before you use PONVORY**

**Do not take PONVORY if:**

- you are allergic to ponesimod or to any of the other ingredients.
- the doctor has advised you that you have a weak immune system.
- you have severe active or chronic infection.
- you have active cancer
- you have moderate or severe liver disease
- you have had a heart attack, chest pain called unstable angina, stroke or mini stroke (transient ischaemic attack can be called TIA), or certain types of heart failure in the last 6 months.
- if you have certain types of heart block or irregular or abnormal heartbeat ('arrhythmia') unless you have a pacemaker.
- you are pregnant or a woman of childbearing potential not using highly effective contraception.

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Do not take PONVORY if any of the above apply to you. If you are not sure if you have any of these conditions, talk to your doctor before taking PONVORY.

**Warnings and precautions**

Talk to your doctor before taking PONVORY if:

- you have an irregular or abnormal heartbeat
- you have slow heart rate
- you have ever had a stroke or other diseases related to blood vessels in the brain
- you have ever suddenly passed out or fainted (syncope)
- you have a fever or infection
- you are unable to fight infections – due to a disease or taking medicines that weaken your immune system.
- you have never had chickenpox or have received the vaccine for chickenpox.  
Your doctor may do a blood test for chickenpox virus. You may need to get the full course of vaccine for chickenpox and then wait 1 month before you start taking PONVORY.
- you have breathing problems
- you have liver problems
- you have diabetes
- you have eye problems – especially an inflammation of the eye called ‘uveitis’
- you have high blood pressure.

If any of the above apply to you (or you are not sure), talk to your doctor before taking PONVORY.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you get any of the following side effects while taking PONVORY:

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**Slow heart rate** (bradycardia or bradyarrhythmia)

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 of PONVORY.

- If you are at increased risk for side effects due to a slowing of your heart rate, your doctor may ask you to stay at the doctor’s office or clinic for at least 4 hours.
- During this time, you will be checked for signs and symptoms of your heart rate slowing down with pulse rate and blood pressure measurements.
- You will also have an ECG at the end of the 4 hours. This is to see if you still have a very slow or decreasing heart rate, or if your ECG is not normal. If any of these happen, you may need to be monitored for a longer period – until these have resolved.
- The same may apply if you are restarting PONVORY after a break in treatment.

**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. These white blood cells fight infection. This will usually go back to normal within 1 week of stopping treatment. Your doctor should review a recent blood test of your white blood cells before you start taking PONVORY.

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Call your doctor immediately or go to the casualty department at your nearest hospital if you have any of these symptoms of an infection during treatment with PONVORY. Also do this for 1 week after your last dose of PONVORY:

- fever
- tiredness
- body aches
- chills
- nausea
- vomiting
- headache with fever, neck stiffness, sensitivity to light, nausea, confusion, (these may be symptoms of meningitis, an infection of the lining around your brain and spine).

**Macular oedema**

PONVORY can cause a problem with your vision called macular oedema (build-up of fluid in the back of the eye [retina] that may cause changes in vision, including blindness).

- Macular oedema can cause some of the same vision symptoms as an MS attack (called 'optic neuritis'). Early on, there may not be any symptoms.
- Be sure to tell your doctor about any changes in your vision.
- If macular oedema happens, it usually starts in the first 6 months after you start taking PONVORY.

Your doctor should test your vision before you start taking PONVORY. Your doctor will also do this any time you notice vision changes during treatment. Your risk of macular oedema is higher if you have diabetes or have had an inflammation of your eye called uveitis.

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- Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- 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

**Liver problems**

PONVORY may cause liver problems. Your doctor will do blood tests to check your liver function before you start taking PONVORY.

Call your doctor immediately or go to the casualty department at your nearest hospital if you have any of the following symptoms of liver problems:

- nausea
- vomiting
- stomach pain
- tiredness
- loss of appetite
- your skin or the whites of your eyes turn yellow
- dark urine.

**Increased blood pressure**

PONVORY may increase blood pressure. Your doctor should will check your blood pressure during treatment with PONVORY.

Exposure to the sun and protection against the sun

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As PONVORY may increase the risk of skin cancer, you should limit your exposure to sunlight and UV(ultraviolet) light, by:

- wearing protective clothing
- regularly applying sunscreen with high sun protection factor.

### **Breathing problems**

Some people who take PONVORY have shortness of breath. Call your doctor straight away if you have new or worsening breathing problems.

### **Swelling and narrowing of the blood vessels in your brain**

A condition called PRES (Posterior Reversible Encephalopathy Syndrome) has happened with medicines acting similarly to PONVORY.

- Symptoms of PRES usually get better when you stop taking PONVORY.  
However, if left untreated, it may lead to a stroke.

Call your doctor immediately or go to the casualty department at your nearest hospital if you have any of the following symptoms:

- sudden severe headache
- sudden confusion
- sudden loss of vision or other changes in your vision
- seizure.

### **Worsening of multiple sclerosis after stopping PONVORY**

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

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## **Elderly**

There is no experience with PONVORY in elderly patients (over 65 years). Talk to your doctor if you have any concerns.

## **Children and adolescents**

PONVORY has not been studied in children and adolescents, therefore it is not recommended for use in children and adolescents aged less than 18 years.

## **Other medicines and PONVORY**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Especially tell your doctor if you take:

- medicines to control your heart rhythm (antiarrhythmics), or blood pressure (antihypertensives), or heartbeat (such as calcium channel blockers or beta-blockers).
- medicines that affect your immune system, due to a possible additive effect on the immune system.

Using PONVORY and other medicines together may affect each other causing serious side effects.

## **Vaccines and PONVORY**

Tell your doctor if you have recently received any vaccinations or if you are planning to receive a vaccination.

- You should avoid receiving live vaccines during treatment with PONVORY.

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- If you receive a live vaccine, you may get the infection the vaccine was meant to prevent.
- PONVORY should be stopped 1 week before and for 4 weeks after receiving a live vaccine.

Also, other vaccines may not work as well when given during treatment with PONVORY.

### **Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking PONVORY.

### ***Pregnancy***

- Do not use PONVORY during pregnancy as there is a risk of harm to your unborn baby.
- Also do not use PONVORY if you are trying to become pregnant or if you are a woman who could become pregnant, and you are not using highly effective contraception.

PONVORY may cause harm to your unborn baby.

### ***Contraception***

Therefore, if you are a woman of childbearing potential:

- Before you start treatment with PONVORY you should have a pregnancy test in order to make sure that you are not pregnant.
- You must use highly effective contraception while taking PONVORY. You should also continue taking your contraception pills for 1 week after you stop taking it to avoid becoming pregnant.

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Talk to your doctor about reliable methods of contraception.

**If you do become pregnant while taking PONVORY, stop taking PONVORY and tell your doctor straight away.**

If you become pregnant within 1 week after you stop taking PONVORY, talk to your healthcare provider.

***Breast-feeding***

Tell your doctor if you are breastfeeding or plan to breastfeed. It is not known if PONVORY passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take PONVORY.

**Driving and using machines**

PONVORY is not expected to have an influence on your ability to drive and use machines.

**PONVORY contains lactose**

PONVORY contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

**PONVORY contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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It is not always possible to predict to what extent PONVORY may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PONVORY affects them.

### **3. How to take PONVORY**

Do not share medicines prescribed for you with any other person.

Always take PONVORY exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with PONVORY will last. Do not stop treatment early because your symptoms may return. If you have the impression that the effect of PONVORY is too strong or too weak, tell your doctor or pharmacist.

The recommended treatment dose of PONVORY 20 mg per day is reached by slowly increasing the dose as instructed in the 14-day Starter Pack.

#### **How to take**

- Take PONVORY exactly as your doctor tells you. Do not change your dose or stop taking PONVORY unless your doctor tells you to.
- **Take only 1 tablet each day.** To help you remember to take your medicine you should take it at the same time each day.
- Swallow the tablet whole
- Take with or without food.

#### **Starter Pack (14-day)**

Only start your treatment with PONVORY using the Starter Pack.

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The purpose of the starter pack is to reduce any side effects due to slowing your heart rate at the start of the treatment.

- Write down the date you start taking the medicine.
- Follow this 14-day treatment schedule.

<b>Starter Pack Day</b>	<b>Daily Dose</b>
Day 1	2 mg
Day 2	2 mg
Day 3	3 mg
Day 4	3 mg
Day 5	4 mg
Day 6	4 mg
Day 7	5 mg
Day 8	6 mg
Day 9	7 mg
Day 10	8 mg
Day 11	9 mg
Day 12	10 mg
Day 13	10 mg
Day 14	10 mg

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## **Maintenance Dose**

- **After** you finish taking the tablets in the Starter Pack, you can continue treatment using the 20 mg maintenance dose.
- On the PONVORY Outer Wallet, write down the date you start taking the 20 mg maintenance dose.

## **If you take more PONVORY than you should**

If you have taken too much PONVORY, call your doctor straight away.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this patient information leaflet with you.

## **If you forget to take PONVORY**

Do not take a double dose to make up for a forgotten tablet.

- If you miss taking 1, 2 or 3 tablets in a row of PONVORY, 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 or maintenance dose as planned.
- If you miss 4 or more tablets in a row of PONVORY, while taking the Starter Pack or the maintenance dose, you need to restart treatment with a new 14-day Starter Pack. Call your doctor if you miss 4 or more doses of PONVORY.

Write down the date you start taking the medicine so you will know if you miss 4 or more doses in a row.

Do not take / receive a double dose to make up for forgotten individual doses.

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**Do not stop taking PONVORY without talking with your doctor first.**

Do not restart PONVORY after stopping it for 4 or more days in a row without seeking advice from your doctor. You will need to restart your treatment with a new Starter Pack.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Not all side effects reported for PONVORY are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking PONVORY, please consult your health care provider for advice.

If any of the following happens, stop taking / using PONVORY and tell your doctor immediately or go to the casualty department at your nearest hospital:

**Frequent side-effects**

- urinary tract infection
- bronchitis
- flu (influenza)
- viral infection of nose, throat, or chest (viral respiratory tract infection)
- viral infection
- herpes zoster virus infection (shingles)
- lung infection (pneumonia)
- spinning sensation (vertigo)
- fever (pyrexia)

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- build-up of fluid in the back of the eye (retina) that may cause changes in vision, including
- blindness (macular oedema)

**Less Frequent side effects**

- slow heart beat (bradycardia)

These are all very serious side effects. If you have them, you may have had a serious reaction to PONVORY. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

**Frequent side effects**

- infection of the nose, sinuses, or throat (nasopharyngitis, respiratory tract infection)
- increased level of liver enzymes in the blood (a sign of liver problems)
- low number of a type of white blood cell, called lymphocytes (lymphopenia)
- high blood pressure (hypertension)
- back pain
- feeling very tired (fatigue)
- feeling dizzy
- being short of breath (dyspnoea)
- high level of cholesterol in the blood (hypercholesterolaemia)
- joint pain (arthralgia)
- arm or leg pain

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- depression
- difficulty sleeping (insomnia)
- cough
- itchy, runny, or blocked nose (rhinitis), infected or irritated throat (pharyngitis, laryngitis), sinus
- infection (sinusitis)
- feeling anxious (anxiety)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- increased level of a protein in the blood that may indicate an infection or inflammation
- (C-reactive protein increased)
- feeling sleepy (somnolence)
- indigestion (dyspepsia)
- swollen hands, ankles, or feet (peripheral oedema)
- migraine
- ligament sprain
- chest discomfort

**Less Frequent side effects**

- high level of potassium in the blood (hyperkalaemia)
- swollen joint
- dry mouth

**Other possible side effects**

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Potential risk of skin cancer. As PONVORY may increase the risk of skin cancer, you should limit your exposure to sunlight and UV (ultraviolet) light, by wearing protective clothing and regularly applying sunscreen with high sun protection factor.

Tell your doctor if you notice any of the above side effects. These are not all the possible side effects of PONVORY. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. If you get side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form,” found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. reporting side effects, you can help provide more information on the safety of PONVORY.

**5. How to store PONVORY**

- Store all medicines out of reach of children.
- Store at or below 30 °C
- Store in the original package / container
- Do not use this medicine after the expiry date which is stated on the carton and blister foil after EXP. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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**6. Contents of the pack and other information**

**What PONVORY contains**

The active substance is ponesimod.

The other ingredients are:

**Tablet core**

Croscarmellose sodium, lactose monohydrate (see “PONVORY contains lactose”), magnesium stearate, microcrystalline cellulose, Povidone K30, silica colloidal anhydrous and sodium laurylsulfate.

**Tablet coating**

Hypromellose 2910, lactose monohydrate, Macrogol 3350, titanium dioxide and triacetin.

***PONVORY 3 mg film-coated tablets***

Iron oxide red (E172) and iron oxide yellow (E172)

***PONVORY 4 mg film-coated tablets***

Iron oxide red (E172) and black iron oxide (E172)

***PONVORY 5 mg film-coated tablets***

Black iron oxide (E172) and iron oxide yellow (E172)

***PONVORY 7 mg film-coated tablets***

Iron oxide red (E172) and iron oxide yellow (E172)

***PONVORY 8 mg film-coated tablets***

Iron oxide red (E172) and black iron oxide (E172)

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*PONVORY 9 mg film-coated tablets*

Iron oxide red (E172) and black iron oxide (E172), iron oxide yellow (E172)

*PONVORY 10 mg film-coated tablets*

Iron oxide red (E172) and iron oxide yellow (E172)

*PONVORY 20 mg film-coated tablets*

Iron oxide yellow (E172)

**What PONVORY looks like and contents of the pack**

**Film-coated tablet (round, biconvex tablet) and various strengths of ponesimod**

**PONVORY Starter Pack**

*PONVORY 2 mg film-coated tablets* are white, round, biconvex, film-coated tablet of 5 mm diameter with “2” on one side and an arch on the other side.

*PONVORY 3 mg film-coated tablets* are red, round, biconvex, film-coated tablet of 5 mm diameter with “3” on one side and an arch on the other side.

*PONVORY 4 mg film-coated tablets* are purple, round, biconvex, film-coated tablet of 5 mm diameter with “4” on one side and an arch on the other side.

*PONVORY 5 mg film-coated tablets* are green, round, biconvex, film-coated tablet of 8,6 mm diameter with “5” on one side and an arch and an “A” on the other side.

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*PONVORY 6 mg film-coated tablets* are white, round, biconvex, film-coated tablet of 8,6 mm diameter with “6” on one side and an arch and an “A” on the other side.

*PONVORY 7 mg film-coated tablets* are red, round, biconvex, film-coated tablet of 8,6 mm diameter with “7” on one side and an arch and an “A” on the other side.

*PONVORY 8 mg film-coated tablets* are purple, round, biconvex, film-coated tablet of 8.6 mm diameter with “8” on one side and an arch and an “A” on the other side.

*PONVORY 9 mg film-coated tablets* are brown, round, biconvex, film-coated tablet of 8.6 mm diameter with “9” on one side and an arch and an “A” on the other side.

*PONVORY 10 mg film-coated tablets* are orange, round, biconvex, film-coated tablet of 8.6 mm diameter with “10” on one side and an arch and an “A” on the other side.

*PONVORY 20 mg film-coated tablets* are yellow, round, biconvex, film-coated tablet of 8,6 mm diameter with “20” on one side and an arch and an “A” on the other side.

PONVORY treatment initiation pack (wallet configuration)

Each blister pack of 14 film-coated tablets for a 2-week treatment schedule contains:

2 film-coated tablets of 2 mg

2 film-coated tablets of 3 mg

2 film-coated tablets of 4 mg

1 film-coated tablet of 5 mg

1 film-coated tablet of 6 mg

1 film-coated tablet of 7 mg

1 film-coated tablet of 8 mg

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD  
Product Proprietary Name: PONVORY® 2/3/4/5/6/7/8/9/10/20 mg



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1 film-coated tablet of 9 mg

3 film-coated tablets of 10 mg

**PONVORY 20 mg film-coated tablets Maintenance Pack**

Pack containing 28 film-coated tablets in a blister pack for a 4-week treatment schedule.

Not all pack sizes may be marketed.

**HOLDER OF CERTIFICATE OF REGISTRATION**

JANSSEN PHARMACEUTICA (PTY) LTD

(Reg. No. 1980/011122/07)

2 Medical Road, Halfway House,

Midrand 1685, South Africa

[ra-medinfoemmarkets@its.jnj.com](mailto:ra-medinfoemmarkets@its.jnj.com)

**Registration numbers**

PONVORY 2 mg film-coated tablets: 56/32.16/0592

PONVORY 3 mg film-coated tablets: 56/32.16/0593

PONVORY 4 mg film-coated tablets: 56/32.16/0594

PONVORY 5 mg film-coated tablets: 56/32.16/0595

PONVORY 6 mg film-coated tablets: 56/32.16/0596

PONVORY 7 mg film-coated tablets: 56/32.16/0597

PONVORY 8 mg film-coated tablets: 56/32.16/0598

PONVORY 9 mg film-coated tablets: 56/32.16/0599

PONVORY 10 mg film-coated tablets: 56/32.16/0600

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD  
Product Proprietary Name: PONVORY® 2/3/4/5/6/7/8/9/10/20 mg



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PONVORY 20 mg film-coated tablets: 56/32.16/0601

**Access to the corresponding Professional Information**

Included in the carton, accompanying this patient information leaflet.