Package leaflet: Information for the patient

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

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ponvory is and what it is used for

What Ponvory is
Ponvory contains the active substance ponesimod. Ponesimod belongs to a group of medicines called sphingosine-1-phosphate (S1P) receptor modulators.

What Ponvory is used for
Ponvory is used to treat adults with relapsing forms of multiple sclerosis (RMS) with active disease. Active disease in RMS is when there are relapses or when MRI (magnetic resonance imaging) results show signs of inflammation.

What is multiple sclerosis
Multiple sclerosis (MS) affects the nerves in the brain and spinal cord (the central nervous system).

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

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

How Ponvory works
Ponvory reduces circulating lymphocytes, which are white blood cells involved in the immune system. It does this by keeping them in the lymphoid organs (lymph nodes). This means that fewer lymphocytes are available to attack the myelin sheath around the nerves in the brain and spinal cord.

Decreasing nerve damage in patients with MS reduces the number of attacks (relapses) and slows down worsening of the disease.

2. What you need to know before you take Ponvory

Do not take Ponvory if
- you are allergic to ponesimod or any of the other ingredients of this medicine (listed in section 6).
- your healthcare professional has told you that you have a severely weakened immune system
- you have had a heart attack, chest pain called unstable angina, stroke or mini-stroke (transient ischaemic attack, TIA), or certain types of heart failure in the last 6 months
- if you have certain types of heart block (abnormal heart tracing on an ECG (electrocardiogram), usually with a slow heartbeat) or irregular or abnormal heartbeat (arrhythmia), unless you have a pacemaker.
- you have severe active infection or active chronic infection
- you have active cancer
- you have moderate or severe liver problems
- you are pregnant or a woman of childbearing potential not using effective contraception.

If you are not sure if you have any of these apply to you, talk to your doctor before taking Ponvory.

Warnings and precautions
Talk to your doctor before taking Ponvory if:
- you have an irregular or abnormal or slow heartbeat
- 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 have an immune system that does not work properly due to a disease or taking medicines that weaken your immune system.
- you have never had chickenpox (varicella) or have not received a 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 (such as severe respiratory disease, pulmonary fibrosis or chronic obstructive pulmonary disease)
- you have liver problems
- you have diabetes. The chance of developing macular oedema (see below) is higher in patients with 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 straight away if you get any of the following side effects while taking Ponvory:

Slow heart rate (bradycardia or bradyarrhythmia)

Ponvory can slow down your heart rate – especially after you take your first dose. You should have an electrocardiogram (ECG, to check your heart's electrical activity) before you take your first dose of Ponvory or before you restart Ponvory after an interruption in treatment.

- If you are at increased risk for side effects due to a slowing of your heart rate, your doctor may monitor your heart rate and blood pressure for at least 4 hours after taking your first dose of Ponvory.
- You will also have an ECG at the end of the 4 hours. If you still have a very slow or decreasing heart rate, you may need to be monitored until these have resolved.

Infections

Ponvory can increase your risk of serious infections that can be life-threatening. Ponvory lowers the number of lymphocytes in your blood. These cells fight infection. Their numbers usually return to normal within 1 week of stopping treatment. Your doctor should review a recent blood test of your blood cells before you start taking Ponvory.

Call your doctor straight away if you have any of these symptoms of an infection during treatment with Ponvory or 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).

The symptoms of macular oedema can be similar to vision symptoms of a 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 check your vision before you start taking Ponvory and also anytime 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.

Call your doctor straight away if you have any of the following:

- blurriness or shadows in the centre of your vision
- a blind spot in the centre of your vision
- sensitivity to light
- unusually coloured (tinted) vision.

Liver problems

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

Call your doctor straight away 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

As Ponvory can increase your blood pressure, your doctor should check your blood pressure regularly during treatment with Ponvory.

Exposure to the sun and protection against the sun

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 improve when you stop taking Ponvory. However, if left untreated, it may lead to a stroke.

Call your doctor straight away 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 be worse compared to before or during treatment. Always talk to your doctor before you stop taking Ponvory. Tell your doctor if you have worsening symptoms of MS after stopping Ponvory.

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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- medicines to control your heart rhythm (antiarrhythmics), blood pressure (antihypertensives), or heart beat (such as calcium channel blockers or beta-blockers medicines that may slow your heart rate).

- medicines that affect your immune system, due to a possible additive effect on the immune system.

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. 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, contraception, and breast-feeding
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 this medicine.

Pregnancy

- Do not use Ponvory during pregnancy. If Ponvory is used during pregnancy there is a risk of harm to your unborn baby.
- Do not use if you are trying to become pregnant or if you are a woman who could become pregnant and you are not using effective contraception.

Women of childbearing potential/Contraception in females

If you are a woman of childbearing potential:
- Your doctor will inform you about the risk of harm to your unborn baby before you start treatment with Ponvory and you should have a pregnancy test to check that you are not pregnant.
- You must use effective contraception while taking Ponvory and for 1 week after you stop taking it.

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 doctor.

Breast-feeding

You should not breast-feed while you are taking Ponvory. This is to avoid a risk of side effects for the baby since Ponvory may pass into breast milk.

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'.

3. How to take Ponvory

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

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.
- Take with or without food.

Treatment initiation pack (14-day)

- **Only** start your treatment with Ponvory using the treatment initiation pack, with which your dose will be gradually increased over 14 days. The purpose of the titration phase is to reduce any side effects due to slowing your heart rate at the start of treatment.
- Write down the date you start taking the medicine next to day 1 on the Ponvory treatment initiation pack.
- Follow this 14-day treatment schedule.

Treatment initiation pack day	Daily dose
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

Maintenance dose

- **After** you finish taking the tablets in the treatment initiation pack, continue treatment using the 20 mg maintenance dose.
- Write down the date you start taking the 20 mg maintenance dose, next to week 1 of the Ponvory 20 mg blister pack.

If you take more Ponvory than you should

If you have taken more Ponvory than you should, call your doctor straight away or go to a hospital straight away. Take the medicine pack and this package 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 up to 3 Ponvory tablets in a row, while taking the treatment initiation pack or the maintenance dose, you can 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 treatment initiation pack dose or maintenance dose as planned.
- If you miss 4 or more Ponvory tablets in a row, while taking the treatment initiation pack or the maintenance dose, you need to restart treatment with a new 14-day treatment initiation pack. Call your doctor straight away 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 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 treatment initiation pack.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be or could become **serious**

Tell your doctor or pharmacist immediately if you notice any of the side effects listed below because they may be signs of serious effects:

Common (may affect up to 1 in 10 people)
- 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)
- build-up of fluid in the back of the eye (retina) that may cause changes in vision, including blindness (macular oedema)
- fits (seizures)

Uncommon (may affect up to 1 in 100 people)
- slow heart beat (bradycardia)

Other side effects

Very common (may affect more than 1 in 10 people)
- 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)

Common (may affect up to 1 in 10 people)
- 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
- 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 (hypoaesthesia)
- 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

Uncommon (may affect up to 1 in 100 people)
- high level of potassium in the blood (hyperkalaemia)
- swollen joint
- dry mouth

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ponvory

Keep this medicine out of the sight and reach of children.

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.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ponvory contains
- The active substance is ponesimod

- The other excipients are:
  Tablet core

  Croscarmellose sodium, lactose monohydrate (see "Ponvory contains lactose"), magnesium stearate, microcrystalline cellulose, Povidone K30, silica colloidal anhydrous and sodium laurilsulfate.

  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)

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
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.

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
1 film-coated tablet of 9 mg
3 film-coated tablets of 10 mg

Ponvory 20 mg film-coated tablets (maintenance pack) (wallet configuration)

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

Marketing Authorisation Holder
Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

Marketing Authorisation Holder (Great Britain only):
Janssen-Cilag Ltd
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Buckinghamshire
HP12 4EG
UK

Manufacturer
Janssen Pharmaceutica NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom (Northern Ireland)
Janssen Sciences Ireland UC
Tel: +44 1 494 567 444

For information in large print, tape, CD or Braille, telephone 0800 7318450.

This leaflet was last revised in May 2023.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu