Janssen Neuroscience

PHARMACEUTICAL COMPANIES OF Johnson&Johnson

PONVORY®▼(ponesimod)

PATIENT/CAREGIVER GUIDE

Important things to remember about Ponvory (ponesimod) treatment

▼This medicinal product 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.
For more information, see the section on reporting of side effects.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt

Alternatively, to report Suspected Adverse Drug Reactions, contact Janssen's Local Representative, AM Mangion, on the following:
Phone (24/7): 00356 2397 6333
Email: pv@ammangion.com
Address: AM Mangion Ltd, Mangion Building, N/S Off Valletta Road, Luqa, LQA 6000, MALTA

For further information please contact Janssen's Local Representative, AM Mangion Medical Information, by using one of the following methods:
Phone: 00356 2397 6888
Email: medicalaffairs@ammangion.com
Website: www.ammangion.com.mt

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Introduction

- This guide contains important information about Ponvory (ponesimod) dosing, side effects and identified and potential risks, including guidance relating to pregnancy
- Read this guide and the leaflet which is inside your Ponvory medication package thoroughly before you start your treatment. Keep this guide together with the package leaflet as you may need to refer to it during treatment

Ponvory should not be used during pregnancy or if you are of childbearing potential and not using effective contraception. If you are of childbearing potential, you will also be given a Pregnancy Reminder Card for further information; please read this card as it contains important information.

What is Ponvory, what is it used for, and how does it work?

What is Ponvory?

Ponvory contains an active substance called ponesimod. It belongs to a group of medicines known as sphingosine-1-phosphate (S1P) receptor modulators.

What is Ponvory used for?

Ponvory is used to treat adults with relapsing multiple sclerosis (RMS) with active disease.

What is multiple sclerosis?

Multiple sclerosis (MS) is a long-term autoimmune disease that affects the nerves in the brain and spinal cord, which together are known as the central nervous system.

- Normally, a protective layer called myelin covers the nerve fibres in the central nervous system
- In MS, the body's immune system mistakenly attacks the protective layer of myelin, causing inflammation and damage. This breakdown in the myelin stops the nerves from working properly and results in the range of symptoms seen in MS

Relapsing MS is a type of MS where these attacks on myelin are repeated (known as relapses) causing symptoms to occur. These symptoms may disappear completely after the relapse, but some symptoms may remain due to permanent damage to the nervous system.

How does Ponvory work?

Ponvory reduces the number of 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.

Starting treatment with Ponvory

Heart monitoring

- Before you start treatment, your doctor will check your heart using an electrocardiogram (ECG). This is to determine if you have any existing heart conditions. For certain heart conditions, your doctor will monitor you for at least 4 hours after your first dose of Ponvory
- You should tell your doctor immediately if you experience any signs or symptoms of a slow heart rate (such as dizziness, vertigo, nausea or palpitations) after your first dose of Ponvory

Vaccinations

- Your doctor will check whether you are protected against chickenpox. If you are not, you may need to have the chickenpox vaccination at least 4 weeks before starting treatment with Ponvory

Blood tests

- Before starting treatment your blood may be tested to check your blood cell count and your liver function, if these have not been measured recently (within the last 6 months)
- Blood testing may also be required after stopping prior therapy

Vision

- Before starting treatment, your doctor will check your vision and examine the back of your eye

Starting treatment with Ponvory

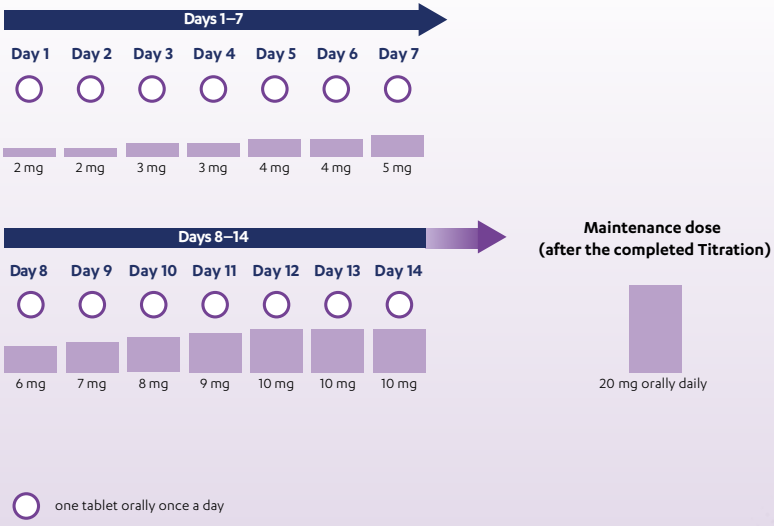
Seizure/Epilepsy

- Before starting treatment, you should tell your doctor if you have ever experienced a seizure or have a family history of epilepsy

Treatment initiation

- Your treatment with Ponvory will start with a 14-day treatment initiation pack. You should follow the 14-day titration schedule as outlined below and within the 14-day treatment initiation pack:

Dose titration



While you are taking Ponvory

Treatment interruptions

- You need to tell your doctor **if you miss 4 or more consecutive days** of Ponvory. You should not restart Ponvory treatment without talking to your doctor, as you will need to restart treatment with a new treatment initiation pack and your doctor may need to obtain another ECG

Blood pressure

- Your blood pressure will be checked regularly while you are taking Ponvory

Infection

- Tell your doctor immediately about any signs or symptoms of infection (such as fever, or flu-like symptoms) while you are taking Ponvory and for up to 1 week after stopping treatment

Visual symptoms

- Tell your doctor immediately about any changes to your vision while taking Ponvory and for up to 1 week after stopping treatment

Liver impairment

- Tell your doctor immediately about any signs or symptoms of liver impairment (such as nausea, vomiting, stomach pain, tiredness, loss of appetite, yellowing of the skin or whites of the eyes, or dark urine) while you are taking Ponvory

While you are taking Ponvory

Breathing problems

- Tell your doctor immediately about any signs or symptoms of new or worsening breathing problems (such as shortness of breath) whilst you are taking Ponvory

Skin cancer

- Skin cancers have been reported in patients treated with Ponvory
- Tell your doctor immediately if you develop any skin nodules (such as shiny, pearly nodules), patches or open sores that do not heal within the usual timelines (weeks of developing). Other symptoms of skin cancer may include abnormal growth or changes in skin tissue (such as unusual moles) with a change in colour, shape or size over time
- You should limit your exposure to sunlight and ultraviolet (UV) light; for example, by wearing protective clothing and regularly applying sunscreen with a high sun protection factor (SPF)

Neurological changes

- Tell your doctor immediately if you develop any signs or symptoms of neurological changes (such as sudden severe headache, sudden confusion, sudden loss of vision or other changes in vision, or seizure) while taking Ponvory
- Patients should inform their prescriber about a pre-existing history or family history of epilepsy.

Women of Childbearing Potential

- Do not use Ponvory during pregnancy, while breastfeeding, or if you are of childbearing potential and not using effective contraception
- Before starting treatment with Ponvory:
  - Your doctor will explain the risks of harmful effects to the unborn baby if you become pregnant while on treatment, both before you start Ponvory and regularly thereafter
  - You must have a negative pregnancy test confirmed by your doctor
- You must be using effective contraception during treatment and for at least 1 week after stopping treatment with Ponvory. Talk to your doctor about reliable methods of contraception
- If you stop taking Ponvory due to pregnancy or while attempting to conceive, your MS symptoms may return. This will be explained to you by your doctor
- You must tell your doctor immediately if you become pregnant while taking Ponvory and for up to 1 week after stopping treatment
- You must immediately stop treatment with Ponvory if you become pregnant
- Refer to the pregnancy-specific patient reminder card for further information and guidance related to contraception, pregnancy and breastfeeding

Reporting of side effects

Ponvory is a new medicine and its safety is being closely monitored. Contact your doctor, pharmacist or nurse if you experience side effects with any medication you are taking. This includes any side effects that are not listed on the information leaflet that comes with this medication.

Reporting information:
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Pregnancy reporting information:
Pregnancy cases associated with PONVORY treatment may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,
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