

PONVORY™
(ponesimod tablets)

PATIENT/ CAREGIVER GUIDE

Important things to remember about PONVORY™ treatment

INTRODUCTION

- This Guide gives important information about treatment with PONVORY™.

Read this Guide and the Patient Medication Information (which is inside your PONVORY™ medication package) thoroughly before you start treatment.

- Keep this Guide together with the Patient Medication Information as you may need to refer to it during the PONVORY™ treatment.

PONVORY™ must not be used during pregnancy or by women of childbearing potential not using highly effective contraception.

What is PONVORY™ used for?

PONVORY™ is used to treat adults with Relapsing Remitting Multiple Sclerosis (RRMS).

What is multiple sclerosis?

Multiple sclerosis is a disease that affects the nerves in the brain and spinal cord, which together are known as the central nervous system. The nerves in the central nervous system are covered by a protective sheath called as myelin.

In multiple sclerosis, the body's immune system mistakenly attacks the protective layer of myelin, causing inflammation and damage. Unpredictable relapses (which are also known as attacks) with remitting periods in between, is called RRMS.

How does PONVORY™ work?

PONVORY™ contains ponesimod. Ponesimod binds to certain receptors on your white blood cells. This keeps the white blood cells in your body's lymph nodes and lowers the number of white blood cells circulating in your body. How exactly PONVORY™ works is not known, but it may be due to less white blood cells entering your central nervous system where they could cause inflammation and damage to the protective coating around the nerves in the brain and spinal cord.

STARTING TREATMENT WITH PONVORY™

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PONVORY™. Talk about any health conditions or problems you may have.

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

Seizure/Epilepsy:

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

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 an ECG should be performed by your doctor

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 light; for example, by wearing protective clothing and regularly applying sunscreen with a high sun protection factor

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®)

Pregnancy and Contraception: You must not become pregnant while taking PONVORY™. If you become pregnant while taking PONVORY™, stop taking it and tell your doctor right away. PONVORY™ may harm your unborn baby.

- Do not use PONVORY® during pregnancy, while breastfeeding, or if you are of childbearing potential and not using effective contraception
- Before starting treatment, your doctor should perform a pregnancy test to confirm that you are not pregnant
- If you are of childbearing age and you might get pregnant, you should use effective birth control methods during treatment and for at least 1 week after stopping PONVORY™. Ask your doctor about options of effective birth control

AFTER STOPPING PONVORY™ TREATMENT:

- PONVORY™ will stay in your body for about 1 week after you stop taking it. Your white blood cell count may remain low during this time and for up to 2 weeks after. The side effects described in the Patient Medication Information, provided with your medication, may still occur.
- Your symptoms of Multiple Sclerosis can return and may become worse compared to before you started treatment or during treatment. Tell your doctor if your symptoms become worse after you stop taking PONVORY™. (Always talk to your doctor before you stop taking Ponvory.)
- You must not become pregnant for at least 1 week after you stop taking PONVORY™.



Adverse events reporting guidance:

The National Pharmacovigilance Centre (NPC)- Saudi Food and Drug Authority (SFDA)

Email: npc.drug@sFDA.gov.sa

Telephone: 19999

Online: <http://ade.sFDA.gov.sa>

For full prescribing information, please refer to the datasheet or contact Johnson & Johnson Middle East FZ-LLC (Riyadh)

Address: Prince Muhammed Bin Abdulaziz Rd, Tower B, Level 30, Olaya towers.

Office Tel 00966-11-4339133

Postal address: P O Box 65305 Riyadh 11556, Saudi Arabia

To report Adverse Events/Product Complaint or any Medical Information Inquiries, please contact us at: Email: GCC-PV2@its.jnj.com

Hotline: 00966540015811

