PONVORY™
(ponesimod tablets)

HEALTHCARE PROFESSIONAL CHECKLIST

Important things to remember
BEFORE, DURING AND AFTER
PONVORY™ Treatment

This risk minimization activity has been reviewed and approved by the Saudi FDA Version 2.0, 03/2026, AR-PI-00923-1

INTRODUCTION

- This Checklist is intended to assist with management of patients on PONVORY™ treatment with important points to remember before, during, and after PONVORY™ treatment.
- A Patient/Caregiver Guide and Pregnancy-specific Patient Reminder Card have also been developed by Juvisé Pharmaceuticals which should be given to the patient during your discussions to inform them about their PONVORY™ treatment.

INDICATION OF USE

PONVORY™ (ponesimod) is indicated for:

The treatment of adult patients with relapsing remitting multiple sclerosis (RRMS).

PONVORY™ should only be prescribed by neurologists who are experienced in the treatment of multiple sclerosis and are knowledgeable of the efficacy and safety profile of PONVORY™ and are able to discuss benefits/harms with patients.

Limitations of Use for the Geriatrics Population (≥ 65 years of age): Clinical studies of PONVORY™ did not include patients aged 65 years and older. Therefore, it is not known whether the safety profile and efficacy differ in elderly patients compared to younger patients.

CONTRAINDICATIONS

PONVORY™ is contraindicated in:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Patients with increased risk of opportunistic infections, including those who are immunocompromised due to treatment (e.g., antineoplastic, immunosuppressive or immunomodulating therapies, total lymphoid irradiation, or bone marrow transplantation) or disease (e.g., immunodeficiency syndrome).
- Patients with severe active infections including active bacterial, fungal or viral infections (e.g., hepatitis, tuberculosis), until resolution of the infection.
- Patients with known active malignancies, except localized basal cell carcinoma of the skin.
- Patients who have in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure.
- Patients with presence of Mobitz Type II second-degree atrioventricular (AV) block or higher-grade AV block, sick-sinus syndrome, or sinoatrial heart block unless the patient has a functioning pacemaker.
- Patients with moderate or severe hepatic impairment (Child-Pugh Class B and C).
- During pregnancy and in women of childbearing potential not using highly effective contraception.
- Patients with unstable ischemic heart disease, cardiac decompensated failure occurring more than 6 months prior to treatment initiation, history of cardiac arrest, cerebrovascular disease (TIA, stroke occurring more than 6 months prior to treatment initiation), and uncontrolled hypertension, since significant bradycardia may be poorly tolerated in these patients, treatment is not recommended.

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ASSESSMENTS PRIOR TO INITIATING PONVORY™ TO GUIDE PATIENT TREATMENT

☐ **Complete Blood Count**

Review results of a complete blood count (CBC) with differential White Blood Cell (WBC) count obtained within the last 6 months.

☐ **Liver Function Tests**

PONVORY™ is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh Class B and C). Review results of transaminase (ALT/AST) and bilirubin levels obtained within the last 6 months.

☐ **Pregnancy Test**

PONVORY™ is contraindicated during pregnancy and in women of childbearing potential not using highly effective contraception. Before initiation of treatment in women of childbearing potential, a negative pregnancy test result must be available.

Counsel women of childbearing potential to discontinue treatment with PONVORY® at least 1 week before attempting to conceive.

Explain to the patient that their disease activity may return when treatment with PONVORY® is discontinued due to pregnancy or attempting to conceive.

Instruct women receiving PONVORY® that they should not breastfeed.

☐ **Ophthalmic Evaluation**

PONVORY™ increases the risk of macular edema. Obtain an evaluation of the fundus, including the macula. PONVORY® should not be initiated in patients with macular oedema until resolution and Instruct patients to report changes in vision.

☐ **Cardiac Evaluation**

PONVORY™ is contraindicated in patients with presence of Mobitz Type II second-degree AV block or higher-grade AV block, sick-sinus syndrome, or sinoatrial heart block unless the patient has a functioning pacemaker. Obtain an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present. First-dose monitoring is recommended for patients with certain pre-existing cardiac conditions:

- Sinus bradycardia (HR <55 beats per minute [bpm])
- First- or second-degree (Mobitz Type I) AV block; or
- A history of myocardial infarction or heart failure occurring more than 6 months prior to treatment

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ASSESSMENTS PRIOR TO INITIATING PONVORY™ TO GUIDE PATIENT TREATMENT

☐ Current or Prior Medications

PONVORY™ is contraindicated in patients with increased risk of opportunistic infections, including those who are immunocompromised due to treatment, e.g., antineoplastic, immunosuppressive or immunomodulating therapies. If there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects before initiating treatment with PONVORY™.

☐ Vaccinations

Test patients for antibodies to varicella zoster virus (VZV) before initiating PONVORY™; a full course of VZV vaccination for antibody-negative patients is recommended prior to commencing treatment with PONVORY™. VZV vaccination is only indicated if the VZV antibody test is negative. The full course of VZV vaccination should be completed at least 4 weeks before starting PONVORY®.

☐ Active Infection

Delay the initiation of PONVORY™ in patients with severe active infection until resolved.

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First-dose monitoring

First-dose monitoring is recommended for patients with certain pre-existing cardiac conditions:

- Sinus bradycardia (HR <55 beats per minute [bpm])
- First- or second-degree (Mobitz Type 1) AV block or
- A history of myocardial infarction or heart failure occurring more than 6 months prior to treatment

If first-dose monitoring for patients with pre-existing cardiac conditions is required, follow the steps outlined below:

If first-dose monitoring is required, monitor for a minimum of 4 hours

- ☐ Administer the first dose of PONVORY™ in a setting where resources to appropriately manage symptomatic bradycardia are available
- ☐ Monitor patients for signs and symptoms of bradycardia for 4 hours after the first dose with a minimum of hourly pulse and blood pressure checks
- ☐ Obtain an ECG in patients at the end of the 4-hour observation period

Are Any Of These Abnormalities Present?

- ☐ Is the patient's HR <45 bpm at 4 hours postdose?
- ☐ at 4 hours postdose?

  Does the patient's ECG show new-onset second-degree or higher AV block at 4 hours postdose?

YES → Extend monitoring until resolution of findings (even in the absence of symptoms)

NO

Are Any Of These Abnormalities Present?

- ☐ Have any postdose symptomatic bradycardia, bradyarrhythmia or conduction-related symptoms occurred in the patient?
- ☐ Is the patient's ECG 4 hours postdose showing QTc ≥500 ms?

NO → **First-dose monitoring is complete**

YES

- ☐ Is pharmacological treatment required?

NO → Initiate appropriate management, begin continuous ECG monitoring and continue monitoring until symptoms have resolved

YES

- ☐ Continue monitoring overnight and repeat 4-hour monitoring after the second dose

bpm beats per minute; ECG electrocardiogram; HR, heart rate: QTc, Heart-rate-corrected QT interval.

☐ The patient does not have applicable pre-existing cardiac conditions and therefore first-dose monitoring is not required

Adapted from the product monograph

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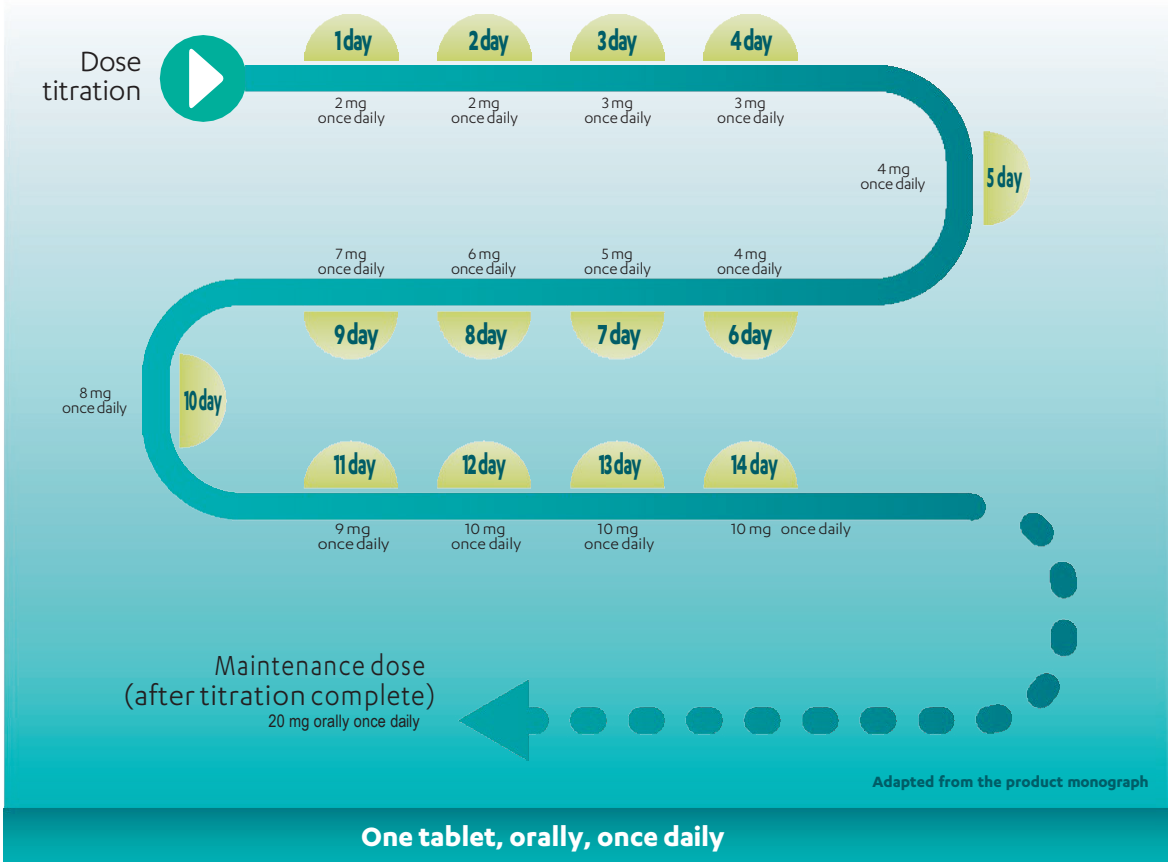
PONVORY™ TREATMENT: TITRATION DOSE AND MAINTENANCE DOSE

Treatment initiation

Dose escalation at treatment initiation
Initiate treatment with the 14-day treatment initiation pack. Start treatment on Day I with one 2 mg tablet orally once daily and progress with the 14-day titration schedule outlined in the following diagram:



- After dose titration is complete, the recommended maintenance dose of PONVORY™ is one 20 mg tablet taken orally once daily.

Re-initiation of PONVORY™ therapy following treatment interruption during dose titration or maintenance period

- Interruption during treatment, especially during up-titration, should be avoided, however:
  - If fewer than 4 consecutive doses are missed, resume treatment with the first missed dose
  - If 4 or more consecutive doses are missed, re-initiate treatment with Day 1 (2 mg) of the titration regimen (using a new treatment initiation pack)
- If ponesimod therapy is discontinued for 4 or more consecutive days, the effects on heart rate and AV conduction may recur on reintroduction of ponesimod treatment and the same precautions as for the first dose should apply. During treatment initiation or maintenance, if treatment needs to be reinitiated with Day 1 of the titration regimen, first-dose monitoring must be completed in patients for whom it is recommended.

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PONVORY™ TREATMENT INITIATION RECOMMENDATIONS

- [ ] Obtain an ECG in all patients to determine whether preexisting conduction abnormalities are present.
  - In all patients, a dose titration is recommended for initiation of PONVORY™ treatment to mitigate cardiac effects.
  - In patients with sinus bradycardia, first- or second-degree [Mobitz type I] AV block, or a history of myocardial infarction or heart failure with onset more than 6 months prior to initiation, ECG testing and first dose monitoring is recommended.

- [ ] PONVORY™ is not recommended in patients with a history of cardiac arrest, cerebrovascular disease (TIA, stroke occurring more than 6 months prior to treatment initiation), uncontrolled hypertension or untreated sleep apnea, since significant bradycardia may be poorly tolerated in these patients. If treatment is considered, advice from a cardiologist should be sought prior to initiation of treatment in order to determine the most appropriate monitoring strategy.
  - Use of PONVORY™ in patients with a history of recurrent syncope or symptomatic bradycardia should be based on an overall benefit risk assessment. If treatment is considered, advice from a cardiologist should be sought prior to initiation of treatment in order to determine the most appropriate monitoring.
  - Experience with PONVORY™ is limited in patients receiving concurrent therapy with drugs that decrease heart rate (e.g., beta blockers, non-dihydropyridine calcium channel blockers - diltiazem and verapamil, and other drugs that may decrease heart rate such as digoxin). Concomitant use of these drugs during PONVORY™ initiation may be associated with severe bradycardia and heart block. Because of the potential additive effect on heart rate, treatment with PONVORY™ should generally not be initiated in patients who are concurrently treated with these substances. If treatment is considered, advice from a cardiologist should be sought prior to initiation of treatment to assess suitability of treatment and to determine the most appropriate monitoring:
    - Bradyarrhythmia effects are more pronounced when PONVORY™ is added to beta-blocker therapy. For patients receiving a stable dose of a beta blocker, the resting heart rate should be considered before introducing PONVORY™ treatment. If the resting heart rate is >55 beats per minute (bpm) under chronic beta blocker treatment, PONVORY™ can be introduced. If resting heart rate ≤ 55 bpm, initiation of treatment with PONVORY™ is not recommended. Depending on the benefit-risk, the beta-blocker may be interrupted until the baseline heartrate is >55 bpm. Treatment with PONVORY™ can then be initiated and treatment with a beta-blocker can be reinitiated after PONVORY™ has been up titrated to the target maintenance dosage. If treatment with PONVORY™ is considered in patients who are under chronic beta-blocker treatment, they should be monitored during treatment initiation according to procedures similar to those recommended below for patients with pre-existing cardiac conditions.
    - For patients taking other drugs that decrease heart rate, treatment with PONVORY™ should generally not be initiated without consultation from a cardiologist because of the potential additive effect on heart rate.

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DURING TREATMENT

☐ CARDIAC CONSIDERATIONS

Bradyarrhythmia and Atrioventricular Conduction Delays

- Since initiation of PONVORY™ treatment results in a transient decrease in heart rate and atrioventricular (AV) conduction delays, an up-titration scheme must be used to reach the maintenance dosage of PONVORY™ 20 mg.

Reduction in Heart Rate

- After the first dose of PONVORYTM, the decrease in heart rate (HR) typically begins within an hour and reaches its nadir within 2-4 hours. The heart rate typically recovers to baseline levels 4-5 hours after administration of the first dose. The mean decrease in heart rate on Day 1 of dosing was 6 bpm. With up-titration after Day 1, the decrease in heart rate is less pronounced.

Atrioventricular Conduction Delays

- Initiation of PONVORYTM treatment has been associated with transient atrioventricular conduction delays that follow a similar temporal pattern as the observed decrease in heart rate during dose titration.

QTc Prolongation

- If treatment with PONVORY™ is considered in patients with pre-existing significant QT prolongation, advice from a cardiologist should be sought prior to initiation of treatment in order to determine the most appropriate monitoring strategy. In patients with atrial flutter/fibrillation or arrhythmias treated with Class Ia or Class III anti-arrhythmic drugs, advice from a cardiologist should be sought prior to initiation of treatment in order to determine the most appropriate monitoring strategy.

Blood pressure considerations

- Blood pressure should be monitored during treatment with PONVORY™ and managed appropriately.

☐ HEPATIC/BILIARY/PANCREATIC

Considerations relating to liver function

- Elevations of transaminases (AST/ALT) may occur in PONVORY™-treated patients. Recent (i.e., within last 6 months) transaminase and bilirubin levels should be reviewed before initiation of PONVORY™ therapy. During treatment with PONVORY™, liver transaminases (ALT/AST) and bilirubin levels should be evaluated within the first 3 months of starting treatment, and periodically or as clinically indicated thereafter. The benefits and risks of treatment should be re-assessed prior to re-initiation of treatment. When re-initiating treatment, consider all relevant assessments and monitoring for treatment initiation. Patients who develop symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, rash with eosinophilia, or jaundice and/or dark urine during treatment, should be monitored for hepatotoxicity. PONVORY™ should be discontinued if significant liver injury is confirmed.

DURING TREATMENT

CONSIDERATIONS RELATING TO IMMUNOSUPPRESSIVE EFFECT

Peripheral blood lymphocyte counts

- PONVORY™ causes a dose-dependent reduction in peripheral lymphocyte count to 30-40% of baseline values due to reversible sequestration of lymphocytes in lymphoid tissues.
- PONVORY™ may therefore increase the risk of infections. Before initiating treatment with PONVORY™, results from a recent complete blood count with differential (i.e., within 6 months or after discontinuation of prior therapy) should be reviewed. In addition, during treatment with PONVORY™, the following should be considered:
    - Periodic assessments of CBC. Absolute lymphocyte counts <0.2 x 109/L, if confirmed, should lead to interruption of PONVORY™ therapy until the level reaches >0.8 x 109/L. Re-initiation of PONVORY™ can then be considered.
    - Suspension of treatment with PONVORY™ should be considered if a patient develops a serious infection until resolution of the infection. Patients receiving PONVORY™ should be instructed to promptly report symptoms of infections to their physician to facilitate early and effective diagnostic and therapeutic strategies.
- Initiation of treatment with PONVORY™ should be delayed in patients with severe active infection until resolution.

Herpes Viral Infections

- Physicians should be vigilant for clinical symptoms that may be suggestive of serious herpetic infections. Cases of herpes viral infection have been reported in the development program of PONVORY™.

Cryptococcal Infections

- Physicians should be vigilant for clinical symptoms or signs of cryptococcal meningitis (CM).
- Patients with symptoms or signs consistent with a cryptococcal infection should undergo prompt diagnostic evaluation and treatment. PONVORY™ treatment should be suspended until a cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.

Progressive Multifocal Leukoencephalopathy

- Progressive multifocal leukoencephalopathy (PML) is an opportunistic viral infection of the brain caused by the JC virus (JCV). Physicians should be vigilant for clinical symptoms or MRI findings that may be suggestive of PML. MRI findings may be apparent before clinical signs or symptoms. If PML is suspected, treatment with PONVORY™ should be suspended until PML has been excluded. If PML is confirmed, treatment with PONVORY™ should be discontinued.

Prior and Concomitant Treatment with Anti-neoplastic, Immune-modulating, or Immunosuppressive therapies

- Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects.

DURING TREATMENT

☐ VACCINES

- Patients without a healthcare professional confirmed history of chickenpox (varicella) or without documentation of a full course of vaccination against varicella zoster virus (VZV) should be tested for antibodies to VZV before initiating PONVORY™ treatment. Delay treatment with PONVORY™ for 4 weeks after vaccination to allow the full effect of vaccination to occur.
- Due to the immunosuppressive properties of PONVORY™, vaccination against HPV should be considered prior to treatment initiation with PONVORY™ taking into account vaccination recommendations.

Unintended Additive Immunosuppressive Effects from Prior Treatment with Immunosuppressive or Immune-modulating Therapies

- When switching from drugs with prolonged immune effects, the half life and mode of action of these drugs must be considered in order to avoid unintended additive effects on the immune system while at the same time minimizing risk of disease reactivation, when initiating PONVORY™.
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☐ NEOPLASMS

- One case of malignant melanoma and two cases of basal cell carcinoma were reported in PONVORY™ treated patients. An increased risk of cutaneous malignancies has been reported in association with another S1P receptor modulator. Physicians and patients should remain alert for the potential development of skin malignancies. Periodic cancer screenings are recommended as per standard of care. Patients should be informed against exposure to sunlight without protection and avoid concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.

☐ REPRODUCTIVE HEALTH: MALE AND FEMALE POTENTIAL

For women of childbearing potential

Females

- PONVORY™ is contraindicated in women of childbearing potential not using highly effective contraception. Before initiation of PONVORY™ treatment in women of childbearing potential, a negative pregnancy test result must be available, and women should be counseled on the potential for a serious risk to the fetus and the need for highly effective contraception during treatment with PONVORY™.

☐ RESPIRATORY CONSIDERATIONS

- PONVORY™ should be used with caution in patients with severe respiratory disease, pulmonary fibrosis and chronic obstructive pulmonary disease (including untreated sleep apnea). Spirometric evaluation of respiratory function should be performed during therapy with PONVORY™ if clinically indicated.

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DURING TREATMENT

☐ NEUROLOGICAL CONSIDERATIONS

Posterior Reversible Encephalopathy Syndrome

- Rare cases of posterior reversible encephalopathy syndrome (PRES) have been reported in patients receiving a sphingosine 1 phosphate (S1P) receptor modulator. Should a PONVORYTM treated patient develop any unexpected neurological or psychiatric symptoms/signs (e.g., cognitive deficits, behavioral changes, cortical visual disturbances, or any other neurological cortical symptoms/ signs), any symptom/sign suggestive of an increase of intracranial pressure, or accelerated neurological deterioration, the physician should promptly schedule a complete physical and neurological examination and should consider a MRI.

Seizures

- Caution should be exercised when administering PONVORY™ to patients with pre-existing seizure disorder.

☐ OPHTHALMIC EVALUATION

Macular Edema

- PONVORY™ increases the risk of macular edema. An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients before starting treatment and again at any time if a patient reports any change in vision while on PONVORY™ therapy. Continuation of PONVORY™ therapy in patients with macular edema has not been evaluated.

Macular Edema in Patients with a History of Uveitis or Diabetes Mellitus

- Patients with a history of retinal diseases, uveitis and patients with diabetes mellitus are at increased risk of macular edema during therapy with S1P receptor modulators. Therefore, these patients should have regular follow up examinations of the fundus, including the macula, during treatment with PONVORY™.

☐ PSYCHIATRIC

Depression and Suicide

- Depression and suicidal ideation are known to occur at an increased frequency in MS patients. Patients treated with PONVORY™ should be advised to immediately report any symptoms of depression and/or suicidal ideation to their prescribing physicians.

Additional considerations

- Provide all patients with the patient/caregiver guide
- Provide all patients with the pregnancy-specific patient reminder card if appropriate

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AFTER TREATMENT DISCONTINUATION

☐ CARDIAC CONSIDERATIONS

- Observe patients with pre excesting cardiac issues for any severe exacerbation or return of cardiac condition activity upon PONVORY® discontinuation and appropriate treatment should be instituted, as required.

☐ HEPATIC/BILIARY/PANCREATIC

Considerations relating to liver function

- Treatment with PONVORY™ should be interrupted with repeated clinically significant increases of Transaminases (AST/ALT) and should only be re-initiated once levels have normalized.

☐ CONSIDERATIONS RELATING TO IMMUNOSUPPRESSIVE EFFECT

- Observe patients with infections for any severe exacerbation or return of high disease activity upon PONVORY® discontinuation and appropriate treatment should be instituted, as required.

☐ VACCINES

- If the use of live attenuated vaccine immunization is required, PONVORY™ treatment should be paused from 1 week prior to 4 weeks after a planned vaccination.

Reversibility of Immune System Effects After Stopping PONVORY™

- After stopping PONVORY™ therapy, ponesimod remains in the blood for up to 1 week. Use of immunosuppressants may lead to an additive effect on the immune system, and therefore caution should be applied up to 1 week after the last dose of PONVORY™.

Severe Exacerbation of Disease After Stopping PONVORY™

- The possibility of severe exacerbation of disease should be considered after stopping PONVORY™ treatment. Patients should be observed for a severe increase in disability upon PONVORY™ discontinuation and appropriate treatment should be instituted, as required.

☐ REPRODUCTIVE HEALTH: MALE AND FEMALE POTENTIAL

Fetal risk

- Based on animal studies, PONVORY™ may cause fetal harm. Because it takes approximately 1 week to eliminate PONVORY™ from the body, women of childbearing potential should use highly effective contraception to avoid pregnancy during and for 1 week after stopping PONVORY™ treatment.

For women of childbearing potential

Females

- PONVORY™ is contraindicated in women of childbearing potential not using highly effective contraception. Before initiation of PONVORY™ treatment in women of childbearing potential, a negative pregnancy test result must be available, and women should be counseled on the potential for a serious risk to the fetus and the need for highly effective contraception during treatment with PONVORY™.

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AFTER TREATMENT DISCONTINUATION

☐ RESPIRATORY CONSIDERATIONS

- PONVORY™ should be used with caution in patients with severe respiratory disease, pulmonary fibrosis and chronic obstructive pulmonary disease (including untreated sleep apnea). Spirometric evaluation of respiratory function should be performed during therapy with PONVORY™ if clinically indicated.

Additional considerations

- Observe patients for a severe exacerbation or return of high disease activity upon PONVORY® discontinuation and appropriate treatment should be instituted, as required.

☐ NEUROLOGICAL CONSIDERATIONS

Posterior Reversible Encephalopathy Syndrome

- Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae. If PRES (posterior reversible encephalopathy syndrome) is suspected, PONVORYTM should be discontinued.

Seizures

- Caution should be exercised when administering PONVORY™ to patients with pre-existing seizure disorder.

☐ OPHTHALMIC EVALUATION

Macular Edema

- A decision on whether PONVORYTM should be discontinued must take into account the potential benefits and risks for the individual patients with Macular edema.

☐ PSYCHIATRIC

Depression and Suicide

- Depression and suicidal ideation are known to occur at an increased frequency in MS patients. Patients treated with PONVORY™ should be advised to immediately report any symptoms of depression and/or suicidal ideation to their prescribing physicians.

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NOTES

NOTES

- [ ] Provide all patients with the Patient/Caregiver Guide
- [ ] Provide patients with the Pregnancy-specific Reminder Card as appropriate

You can request additional materials from Juvisé Pharmaceuticals at the following email address: ponvoryeducationalmaterial@juvise.com.

Adverse events reporting guidance:
SFDA (National Pharmacovigilance center)
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 Cigalah Healthcare Company
Address: Ottman bin affan street, Almamoun building, Ground floor, Pharmacovigilance Department
Office Tel +966-12-6148000
Postal address: P O BOX 19435 Jeddah 21435, Saudi Arabia
To report Adverse Events/Product Complaint or any Medical Information Inquiries, please contact us at:
Email: Drug-Safety@Cigalah.com.sa
Hotline: +966-539455825

Ponvory™ ponesimod once-daily tablets

JUVISE® pharmaceuticals

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