

ZEPOSIA[®]
(ozanimod)

Patient/Caregiver Guide

What ZEPOSIA is and what it is used for

Zeposia is a medicine for multiple sclerosis.

Zeposia contains the active substance ozanimod that belongs to a group of medicines which can reduce the number of certain white blood cells (lymphocytes) circulating freely round the body.

Multiple Sclerosis

Ozanimod is indicated to treat adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease, to decrease the number of episodes of worsening signs and symptoms.

Multiple sclerosis (MS) is a disease in which the immune system (the body's defences, including white blood cells) wrongly attacks the protective coat around the nerves in the brain and spinal cord. This stops the nerves from working properly and may result in symptoms such as numbness, difficulty in walking, and problems with vision and balance.

In relapsing remitting multiple sclerosis, attacks on the nerve cells are followed by periods of recovery. The symptoms may disappear during the recovery periods, but some problems may remain.

Ozanimod helps to protect against attacks on the nerves by stopping certain white blood cells from reaching the brain and spine where they could cause inflammation and damage the nerves' protective coating.

Do Not Take Ozanimod if:

- You are allergic to ozanimod or any of the other ingredients of this medicine;
- Your doctor has told you that you have a severely weakened immune system;
- You have had a heart attack, angina, stroke or mini-stroke (Transient Ischemic Attack - TIA), or certain types of severe heart failure in the last 6 months;
- You have certain types of irregular or abnormal heartbeats (arrhythmia) – your doctor will check your heart before starting treatment;
- You have severe infection such as hepatitis or tuberculosis;
- You have cancer;
- You have severe liver problems;
- You are pregnant or a woman of childbearing potential not using effective birth control.
- You are taking a medicine known as a monoamine oxidase (MAO) inhibitor.

Taking Ozanimod for the First Time

Before you start taking ozanimod, read this Guide carefully as it has important information for you. Keep this Guide as you may need to read it again while taking ozanimod.

Heart Monitoring

Ozanimod can slow down your heart rate. Your doctor will check your heart using an electrocardiogram (ECG) before you start taking ozanimod. If you have a slow heart rate or certain heart conditions, your doctor will monitor you for at least the first 6 hours after your first dose, including hourly checks of your heart rate and blood pressure. Your doctor may obtain an ECG at the start and end of this 6 hour period. Further monitoring may be needed if your heart rate remains slow or if abnormal heart rhythm is observed after this 6 hour period.

Immediately report to your doctor any symptoms of a slow heart rate (such as dizziness, vertigo, nausea or palpitations) after taking ozanimod for the first time. Since other medicines may also slow down your heart rate, it is important to inform all your doctors of all the medicines that you are taking, including ozanimod.

Vaccinations

Your doctor will check if you are protected against chickenpox before you start taking ozanimod. You may need to have the chickenpox vaccination 1 month before you begin taking ozanimod. Certain types of vaccines (live attenuated vaccines) should be avoided during and for 3 months after treatment with ozanimod. Consult your doctor before undergoing any vaccination.

Liver Function Test

Your doctor will check your liver function before you start taking ozanimod.

While Taking Ozanimod

Treatment Interruptions

Do not stop taking ozanimod without talking to your doctor first. Talk to your doctor about how to re-start your treatment if you have stopped taking ozanimod for:

- 1 day or more during the first 14 days of treatment
- more than 7 consecutive days between Day 15 and Day 28 of treatment
- more than 14 consecutive days after Day 28 of treatment.

Your doctor may need to decrease and gradually increase your dose again.

Neurologic Symptoms

If you develop any of the following symptoms while taking ozanimod, consult your doctor straight away:

- sudden severe headaches, confusion, fits (seizures) and loss of vision
- progressive weakness on one side of the body or clumsiness of limbs, vision changes, changes in thinking, memory, awareness, confusion and personality changes

These symptoms may be caused by a rare condition called posterior reversible encephalopathy syndrome (PRES) or a rare infection of the brain called progressive multifocal leukoencephalopathy (PML) respectively.

Infection

While you are taking ozanimod, you may get infections more easily. Tell your doctor right away if you have any signs and symptoms of an infection while you are taking ozanimod, and for up to 3 months after you stop taking ozanimod. Ozanimod may also reduce the number of white blood cells (lymphocytes) circulating round your body. Your doctor may order a blood test to check your level of blood cells before you start taking ozanimod and then check periodically thereafter.

Visual Symptoms

Ozanimod may cause swelling at the back of the eye, a condition that is known as macular oedema. Tell your doctor right away if you have any

symptoms of reduced vision while you are taking ozanimod, and for up to 3 months after you stop taking ozanimod. If you have diabetes or have had inflammation of the eye (uveitis) or retinal disease, your doctor may send you for an eye examination as you may have a higher chance of developing macular oedema.

Pregnancy

Do not use ozanimod if you are pregnant or breast-feeding, or a woman of childbearing potential not using effective birth control. If used during pregnancy, ozanimod can harm the unborn baby. Potential risks include loss of the unborn baby and birth defects.

Before starting treatment with ozanimod:

- Your doctor will explain the potential risks to an unborn baby if you become pregnant while taking ozanimod;
- You must have a negative pregnancy test verified by your doctor before you start treatment. Your doctor will ask you to repeat pregnancy tests at suitable intervals during treatment.
- You must use effective birth control while taking ozanimod, including if your treatment is temporarily put on hold and for 3 months after you stop taking ozanimod.

While taking ozanimod treatment, you must not become pregnant. Your doctor will advise you of the harmful effects to the baby associated with ozanimod treatment and ultrasound exams will be offered if needed. You should stop taking ozanimod 3 months before planning a pregnancy. If you stop taking ozanimod because you are pregnant or planning to have a baby, your disease symptoms may return.

Tell your doctor right away if you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby while taking ozanimod and for 3 months after you stop taking ozanimod.

If you are a woman of childbearing potential, you should also receive the Pregnancy Reminder Card. Please read this card carefully as it contains important information.

Liver Function

Ozanimod can cause abnormal results in liver function tests. Your doctor may order a blood test to check your liver function on the 1st, 3rd, 6th, 9th, and 12th months of taking ozanimod, and then periodically thereafter. Inform your doctor if you notice any unexplained nausea and vomiting, pain on the right side of your stomach area, tiredness, loss of appetite, yellowing of the skin or whites of your eyes or abnormally dark urine, as these could be signs of liver injury.

Blood Pressure

Ozanimod may cause an increase in your blood pressure. Your doctor will check your blood pressure regularly while you are taking ozanimod. Avoid eating foods containing large amounts of tyramine such as aged cheese, cured meats, fermented food and alcoholic drinks, as these can lead to severe high blood pressure.

Certain over-the-counter medicines may also raise your blood pressure when used with ozanimod. Ask your doctor or pharmacist before using any medicines.

Skin Cancer

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

Reporting Side Effects:

If you experience any side effects, including side effects not listed in this Guide, consult your doctor or pharmacist.

