

Zeposia[®] (ozanimod)

Patient/Caregiver Safety information Guide

What is Zeposia® and How Does it Work?

Zeposia® is a medicine to treat adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease. Zeposia® helps to protect against attacks on the nerves by stopping lymphocytes, a type of white blood cell, from reaching the brain and spine where they may cause inflammation and damage the protective coating of nerves.

What is Multiple Sclerosis?

Multiple sclerosis (MS) is a disease in which the immune system (the body's defenses, including white blood cells) wrongly attack 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.

Do Not Take Zeposia® 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 or have had in the past 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.

Taking Zeposia® for the First Time:

Before you start taking Zeposia®, read the package leaflet carefully as it has important information for you. Keep the leaflet as you may need to read it again while taking Zeposia®.



Electrocardiogram

Your doctor will check your heart using an electrocardiogram (ECG) before you start taking Zeposia®. If you have certain heart conditions, your doctor will monitor you for at least the first 6 hours after your first dose, and may obtain an ECG at the start and end of this 6 hour period.



If You Have Low Heart Rate

Your doctor will check your heart rate before you start taking Zeposia®. If required, your doctor will monitor your heart rate for 6 or more hours after taking Zeposia® for the first time and will check your pulse and blood pressure hourly. Immediately report any symptoms of a low heart rate (such as dizziness, vertigo, nausea or palpitations) after taking Zeposia® for the first time. Since other medications may also lower your heart rate, it is important to tell all your doctors that you are taking Zeposia®.

If You Have a Heart Condition

Zeposia® should not be used if you have certain heart conditions such as a heart attack, angina, stroke or mini-stroke (transient ischaemic attack), or certain types of severe heart failure in the last 6 months or if you have certain types of abnormal heartbeats (arrhythmia). Your doctor will check your heart before you start treatment with Zeposia®.



Vaccinations

Your doctor will check if you are protected against chickenpox before you start taking Zeposia®. You may need to have the chickenpox vaccination 1 month before you begin taking Zeposia®.



Liver Function Test

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



Eye Examination

If you have Diabetes, Inflammation of the eye (Uveitis), have now or have ever had retinal disease, your doctor may refer you for an eye examination either before you start or while you are taking Zeposia®.

While Taking Zeposia®:

Treatment Interruptions

Tell your doctor if you stop taking Zeposia®, even if only for a short time. Depending on how long ago you stopped taking Zeposia®, your dose may need to be changed. Your doctor may need to decrease your dose of Zeposia® and then increase it gradually.



Neurologic Symptoms

Tell your doctor right away if you have any signs of neurologic changes such as sudden severe headaches, confusion, seizures or vision changes while you are taking Zeposia®.



Infection

While you are taking Zeposia®, 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 Zeposia®, and for up to 3 months after you stop taking Zeposia®. Zeposia® 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 Zeposia® and then check periodically thereafter.



Visual Symptoms

Tell your doctor right away if you have any symptoms of reduced vision while you are taking Zeposia®, and for up to 3 months after you stop taking Zeposia®.



Pregnancy

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

While Taking Zeposia®: (Continued)

Before starting treatment with Zeposia®:

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



While taking Zeposia® treatment, you must not become pregnant. Your doctor will advise you of the harmful effects to the baby associated with Zeposia® treatment and ultrasound exams will be offered if needed. You should stop taking Zeposia® 3 months before planning a pregnancy.



If you stop taking Zeposia® because you are pregnant or planning to have a baby, your multiple sclerosis 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 Zeposia® and for 3 months after you stop taking Zeposia®.



Liver Function Test

Your doctor may order a blood test to check your liver function on the 1st, 3rd, 6th, 9th, and 12th months of taking Zeposia®, and then periodically thereafter.



Blood Pressure

Your doctor will check your blood pressure regularly while you are taking Zeposia®.



Skin Cancer

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

Reporting Side Effects:



If you experience any side effects, talk to your doctor or pharmacist. You can also report side effects directly to the Israeli Ministry of Health by using the on-line form for reporting adverse events on the Home page of the Ministry of health website: www.health.gov.il or by entering the following link: <https://sideeffects.health.gov.il>

More information regarding how to report side effects can be found in the Patient Information Leaflet.

For more information please contact your doctor or pharmacist. To obtain a copy of this document please contact Bristol-Myers Squibb by phone: 03-5231021 or fax: 03-9226896.

Notes
