

ZEPOSIA[®] ▼
(ozanimod)

Patient/Caregiver Guide

UK

Version 2.0

Important things to remember about ozanimod treatment for patients and caregivers.

▼ 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. See www.mhra.gov.uk/yellowcard for how to report side effects or search for MHRA Yellow Card in the Google Play or Apple App Store.

An electronic copy of this document can be viewed or downloaded from the electronic medicines compendium via www.medicines.org.uk/emc.

If you have any questions or require further information, please contact Bristol-Myers Squibb Medical Information on:

Tel: 0800 731 1736

Email: medical.information@bms.com

Date of preparation: December 2020

RMP/ZEP/002/21-02/M (UK)

Approved by MHRA: February 2021

What is ozanimod and how does it work?

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Ozanimod is a medicine to treat adults with active relapsing remitting multiple sclerosis (RRMS).

What is relapsing remitting multiple sclerosis (RRMS) and how does ozanimod work?

Multiple Sclerosis (MS) is a long-term autoimmune disorder that can cause recurrent episodes of inflammation of the protective myelin layer around nerves. These episodes are called relapses or attacks.

Ozanimod helps to protect against relapses by reducing the number of lymphocytes, a type of white blood cell, from reaching the brain and spine where they may cause inflammation and damage the protective myelin layer around nerves.

Before starting ozanimod treatment

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

Ozanimod may cause birth defects and miscarriage to an unborn baby. 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.

Do not take ozanimod if:

- 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 are pregnant or a woman of childbearing potential not using effective birth control.

The first time you take ozanimod

Heart monitoring

Your doctor will check your heart using an electrocardiogram (ECG) before you start taking ozanimod. If you have certain heart conditions, your doctor will monitor you for at least the first 6 hours after your first dose, including checking your pulse and blood pressure hourly, and will obtain an ECG at the start and end of this 6 hour period.

Immediately report any symptoms of a low heart rate (such as dizziness, vertigo, nausea or palpitations) after taking ozanimod for the first time.

Ozanimod can interact with medicines that slow your heart rate so it is important for you to tell any healthcare professional treating you (for example, dentist, pharmacist, doctor or nurse) that you are receiving 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.

Liver function test

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

While you are taking ozanimod

Treatment interruptions

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

Neurological symptoms

Tell your doctor right away if you have any signs of neurological changes such as accelerated neurological deterioration, sudden severe headaches, confusion, seizures or vision changes while you are taking ozanimod.

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.

Visual symptoms

Tell your doctor immediately if you have any changes in vision while you are taking ozanimod, and for up to 3 months after you stop taking ozanimod.

Liver function test

Ozanimod can cause abnormal results in liver function tests. You will need a blood test at months 1, 3, 6, 9 and 12 during ozanimod treatment and regularly thereafter.

Blood pressure

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

Skin cancer

Ozanimod 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).

While you are taking ozanimod

Pregnancy

Ozanimod may cause birth defects or miscarriage to an unborn baby. 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 and repeated at suitable intervals;
- 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 examinations 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 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 ozanimod and for 3 months after you stop taking ozanimod.

Reporting side effects

The safety of ozanimod is being closely monitored as it is a new medicine. It is important that any side effects are reported, even those not listed in the patient information leaflet that comes with the pack. You can help others by providing more information on the safety of your medication by reporting side effects.

You can report side effects online via the Yellow Card website <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

Any side effects or pregnancies may also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736; E-mail: medical.information@bms.com.

