ZEPOSIA® ▼
(ozanimod)

Patient/Caregiver Guide

UK
Version 3.0

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.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting side effects, you can help provide more information on the safety of this medicine.

An electronic copy of this document can be viewed or downloaded from the electronic medicines compendium via www.medicines.org.uk/emc (Great Britain) and www.emcmedicines.com/en-gb/northernireland (Northern Ireland).

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

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Bristol Myers Squibb™

What is ozanimod and how does it work?

What is ozanimod?

Ozanimod is a medicine to treat adults for the following diseases:

- Multiple sclerosis (MS)
- Ulcerative colitis (UC)

Ozanimod 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.

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.

Ulcerative colitis

Ozanimod is indicated for the treatment of adult patients with moderately to severely active UC.

UC is an inflammatory disease of the bowel, in which the immune system attacks the lining of the intestine, causing symptoms such as abdominal pain, diarrhoea and bleeding.

Ozanimod can help to reduce the signs and symptoms of UC, by reducing the inflammation and stopping certain white blood cells from reaching the intestinal lining.

What is ozanimod and how does it work?

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:

- Within the last 6 months, you have had a heart attack, angina, stroke or ministroke (Transient Ischemic Attack - TIA), or certain types of severe heart failure.
- 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 contraception.

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The first time you take ozanimod

Heart monitoring
Your doctor should check your heart using an electrocardiogram (ECG) before you start taking ozanimod. If you have a low 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 pulse and blood pressure. Your doctor should 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 accelerated neurological deterioration or unexpected neurological and/or psychiatric symptoms/signs such as sudden severe headaches, confusion, seizures, progressive weakness, clumsiness 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).

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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 breastfeeding, or a woman of childbearing potential not using effective contraception. 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 contraception 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 disease related 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.

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- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.
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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.

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