ZEPOSIA® (ozanimod)

Patient/Caregiver Guide

Ireland
Version 4.0

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

Please refer to the 'Reporting Side Effects' section for information on how to report side effects.

An electronic copy of this document can be viewed or downloaded from the Irish medicines compendium via www.medicines.ie (enter 'Zeposia' or 'ozanimod' in the 'Search' box, click on the required medicine, and then click on the 'Ed Material - Patient' tab). It is also available to view or download from www.hpra.ie (enter 'Zeposia' or 'ozanimod' in the 'Find a medicine' search box and then click on 'EdM' next to any of the medicines that appear).

If you have any questions or require further information, please contact Bristol-Myers Squibb Medical Information on:
Tel: 1 800 749 749
Email: medical.information@bms.com

This risk minimisation material fulfils the conditions of the marketing authorisation for ozanimod and has been approved by the Health Products Regulatory Authority (HPRA).

Bristol Myers Squibb®

Date of preparation: April 2025
2084-GB-2500018
Approved by HPRA: June 2025

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 for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease. 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 RRMS, 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 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.

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.

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.

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. Further information can be found under 'Pregnancy Information for Women of Childbearing Potential' in this guide.

The first time you take ozanimod

At the beginning of treatment, ozanimod can cause the heart rate to slow down, which can cause side effects.

Heart monitoring
Your doctor will check your heart using an electrocardiogram (ECG) and check your heart rate 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 may obtain an ECG at the start and end of this 6-hour period.
- Immediately report to your doctor 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.

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While you are 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
- for more than 7 consecutive days between day 15 and day 28 of treatment
- for more than 14 consecutive days after day 28 of treatment.

You will need to start the 'treatment initiation pack' again.

Neurological symptoms

- During treatment, if you develop disturbance of vision, progressive weakness, clumsiness, memory loss or confusion, speak to your doctor straight away.
- Also tell your doctor right away if you believe your MS is getting worse or if you notice any new symptoms during and after stopping treatment with ozanimod, for example changes in mood or behaviour, new or worsening weakness on one side of the body, changes in vision, confusion, memory lapses or speech and communication difficulties. These may be symptoms of a rare infection of the brain called progressive multifocal leukoencephalopathy (PML) or of an inflammatory reaction (known as immune reconstitution inflammatory syndrome or IRIS). If you experience PML, treatment with ozanimod will be stopped. When ozanimod is removed from your body after you stop taking it, you may get a reaction known as IRIS.
- During treatment, if you develop a severe headache, feel confused, or have seizures (fits) and loss of vision, speak to your doctor straight away. These symptoms may be due to a syndrome called posterior reversible encephalopathy syndrome (PRES).

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: e.g. fever, flu-like symptoms, headaches with a stiff neck, sensitivity to light, nausea and/or confusion while you are taking ozanimod, and for up to 3 months after you stop taking ozanimod.

Visual symptoms
Ozanimod may cause swelling at the back of the eye, a condition that is known as macular oedema. 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. If your test results indicate a problem with your liver, you may have to interrupt treatment with ozanimod.

During treatment with ozanimod, if you develop unexplained nausea, vomiting, pain on the right side of the stomach area (abdominal pain), tiredness, loss of appetite, yellowing of your skin or the whites of your eyes (jaundice) and/or dark urine, speak to your doctor straight away. These symptoms may be due to a problem with your liver.

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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).

Pregnancy Information for Women of Childbearing Potential
If used during pregnancy, ozanimod can harm the unborn baby. Potential risks include loss of the unborn baby and birth defects. You must not use ozanimod if you are pregnant or breastfeeding. You must use effective contraception without interruption while taking ozanimod and for at least 3 months after you stop taking it to avoid becoming pregnant.

Before starting treatment with ozanimod:

- Your doctor will explain the potential serious risks associated with ozanimod to an unborn baby.
- 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 will need to use effective contraception. Talk to your doctor about the most effective contraception options available to you.
- Tell your doctor if you are planning to become pregnant. Ozanimod can stay in your body after you stop taking it. You will need to stop treatment at least 3 months before becoming pregnant.

While taking ozanimod treatment, you must not become pregnant. Tell your doctor immediately if you become pregnant or are breastfeeding, or think you may be pregnant whilst taking ozanimod or for 3 months after you stop taking it. Your doctor will advise you of the harmful effects to the baby associated with ozanimod treatment and ultrasound examinations will be offered if needed.

If you stop taking ozanimod because you are pregnant or planning to have a baby, your disease related symptoms may return.

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

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Reporting side effects

It is important that any side effects are reported. You can help others by providing more information on the safety of your medication by reporting side effects.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via HPRA Pharmacovigilance at www.hpra.ie.

Any side effects or pregnancies should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749; E-mail: medical.information@bms.com.

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