

Ozanimod for IBD

Points to remember

- Ozanimod is a safe and effective medicine to treat ulcerative colitis.
- Always attend your scheduled clinic appointments to ensure that you have an approved prescription available when you need to get your next supply of ozanimod.

What is ozanimod and how does it work?

Ozanimod is a medicine known as a 'sphingosine 1-phosphate (S1P) receptor modulator'. The S1P receptor plays an important role in the body's immune response, which causes inflammation if you have a type of inflammatory bowel disease (IBD) known as ulcerative colitis. By changing how the S1P receptor acts, ozanimod reduces inflammation and stops certain white blood cells from reaching the lining of the bowel, allowing it to heal.

Why have I been prescribed ozanimod?

Ozanimod is used to treat moderate to severe ulcerative colitis. It is prescribed if other medicines have not worked or are not suitable for you.

How do I get ozanimod?

Ozanimod is an expensive medicine, so there are strict government restrictions and regulations to make it available at a subsidised (lower) price on the PBS. To ensure you can keep taking ozanimod, you will need to have your IBD assessed every 6 months. This may include regular blood tests and an appointment with your IBD team.

What checks do I need to have before I start taking ozanimod?

Before you start taking ozanimod, your IBD team may request blood tests, including your full blood count and liver function tests. You may be asked to have an electrocardiogram (ECG), and your blood pressure may

be checked. You may need an eye assessment from an optometrist or ophthalmologist. You should tell your IBD team if you have any heart or lung disease, diabetes, eye problems, high blood pressure or have ever had a stroke.

You will also be screened for infections and to check you are up to date with your vaccinations before starting treatment. This screening may include blood tests and a chest x-ray to check your risk of infection. You may be advised to have one or more vaccinations before you start taking ozanimod. Please see the [IBD – Vaccinations information sheet](#) for more information.

Tell your doctor if you are taking or have previously taken any other medicines, as some medicines cannot be taken safely with ozanimod.

What is the normal dose of ozanimod?

You will usually start taking ozanimod using a 7-day initiation pack. Treatment starts with a 230 microgram capsule once a day for the first 4 days, then increases to a 460 microgram capsule once a day for the next 3 days. After these 7 days, you will usually then keep taking a 'maintenance' dose of a 920 microgram capsule once a day, starting on the 8th day. If you miss one or more doses of ozanimod, you should contact your IBD team, as your dosing schedule may need to be adjusted.

Your IBD team will monitor your body's response to this medicine and give you information about your dosage and when to have blood tests done.

How do I take ozanimod?

Ozanimod capsules should be swallowed whole at the same time each day. They can be taken with or without food.

How long will I need to take ozanimod?

If your IBD gets better when you are taking ozanimod, it may be used for the long term.

What checks will I need to have while I am taking ozanimod?

Regular blood tests are very important because ozanimod can interfere with normal bone marrow function and can cause liver complications. Regular blood tests can pick up abnormalities in the blood that may not produce symptoms straight away. When you are taking a stable dose of ozanimod, you may only need blood tests every 3–6 months. Your doctor will check your blood pressure regularly while you are taking ozanimod. You may also be advised to have regular eye examinations while taking ozanimod.

Fertility, pregnancy and breastfeeding

Ozanimod should not be taken during pregnancy because it can be harmful to the unborn baby. Women of childbearing age who are taking ozanimod should use reliable contraception. You should stop taking ozanimod at least 3 months before any planned pregnancy. Tell your doctor if you are thinking of becoming pregnant or find out that you are pregnant.

It is not recommended to breastfeed while taking ozanimod and for 3 months afterwards, while the medicine is still in your body. Talk to your IBD team or lactation nurse before breastfeeding if you have recently stopped taking ozanimod.

What are the possible side effects of ozanimod?

All medicines can cause side effects, although not everyone experiences them. Report any side effects to your IBD team so they can monitor them.

Common side effects:

- **Headaches, aches and pains, fever, flu-like symptoms, nausea (feeling sick) or diarrhoea:** these symptoms will often go away as your body becomes used to the new medicine, but some people may need to swap to a different medicine
- **High blood pressure**
- **Swelling of arms, hands, feet, ankles or legs** because of fluid build-up

- **Cold sores and viral infections of the nose, mouth and throat:** ozanimod may increase your risk of infections such as the common cold, and sometimes other more serious infections. Please contact your doctor or IBD team if you have any symptoms of infection, such as a fever, while taking ozanimod and for up to 3 months after you stop taking it; this can sometimes be because your white blood (immune) cell count is too low, so this may need to be checked
- **Inflammation of the liver:** if this happens, stopping the medicine or changing the dose can bring the results of your liver tests back to normal; you should monitor for signs including yellowing skin, dark urine (wee) and pale stools (poo)
- **Shingles:** this is a painful rash that can occur in people who have previously had chickenpox; if you notice a rash, please see your GP, ideally within the first 3–5 days, as you may need medicine to treat this.

Less common or rare side effects:

- **An allergic reaction to ozanimod, such as a rash:** seek medical attention immediately if you have any swelling of your face, lips, tongue or throat or have difficulty breathing.
- **Macular oedema:** tell your doctor right away if you have any changes in vision, including shadows or blind spots in the centre of your vision, blurred vision, or problems seeing colours or details
- **New or worsening breathing problems**
- **An increased risk of other serious infections, such as tuberculosis, pneumonia, chicken pox and progressive multifocal leukoencephalopathy (PML):** you will be screened for this risk and vaccinated if possible. PML is a viral infection in the brain, with symptoms that include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision and changes in thinking, memory and orientation, leading to confusion and personality changes
- **Posterior reversible encephalopathy syndrome (PRES):** this is a very rare condition affecting the brain; tell your doctor right away if you have sudden severe headaches, confusion, seizures, progressive weakness, clumsiness or vision changes

- There is not yet enough information to know if there is any increased risk of cancer when taking ozanimod; please discuss any concerns you have with your IBD team.

Can I take other medicines while I'm taking ozanimod?

Ozanimod can interact with many types of medicines, which may result in side effects. Your IBD team may ask you for a full list of your medicines, and you should tell your GP, IBD team and pharmacist about any new medicines that you start using.

What can I do to keep myself healthy while taking ozanimod?

- Avoid close contact with people who have transmissible infections. Tell your doctor if you have come into contact with anyone who has an infectious condition, such as chicken pox, shingles, whooping cough or measles.
- You should have the flu vaccine every year and the COVID-19, pneumonia and human papillomavirus (HPV) vaccines according to the recommended schedule. You should not have any 'live' vaccines while taking ozanimod and for some time after stopping it. Please see the [IBD – Vaccinations information sheet](#) for more information.

- Women should have regular cervical screening tests, as recommended by your GP.
- You should use a strong sunscreen and protect your skin when outside. You should not have phototherapy while you are taking ozanimod. Annual skin checks are recommended.
- Always check with your IBD team before starting to take any new medicines, to avoid unwanted interactions with ozanimod.
- Always 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 lower your dose and then increase it gradually.

Contact your IBD team or GP if you have an infection or persistent fever.

This information leaflet has been designed to give you some important information about ozanimod. This information is general and not intended to replace specific advice from your doctor or any other health professional. For more information, please talk to your pharmacist, doctor or IBD nurse.

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This resource was developed in 2023 by the **IBD Patient Information Materials Working Group** that included the following health professionals:

Mayur Garg (Chair, Gastroenterologist)	Susan Connor (Gastroenterologist)	Katherine Healy (Senior Gastrointestinal Dietitian)	Antonina Mikocka-Walus (Specialist Gastrointestinal Psychologist)
Aysha Al-Ani (Gastroenterologist)	Sam Costello (Gastroenterologist)	Vanessa Inserra (IBD Pharmacist)	Marion O'Connor (IBD Clinical Nurse Consultant)
George Alex (Gastroenterologist - Paediatric)	Basil D'Souza (Colorectal Surgeon)	Simon Knowles (Specialist Gastrointestinal Psychologist)	Clarissa Rentsch (IBD Pharmacist)
Vinna An (Colorectal Surgeon)	Alice Day (Senior Gastrointestinal Dietitian)	Taryn Lores (Health Psychologist)	Sally Stockbridge (CCA Consumer Representative)
Jakob Begun (Gastroenterologist)	Kevin Greene (Consumer Representative)	Raphael Luber (Gastroenterologist)	Julie Weldon (CCA Consumer Representative)
Maryjane Betlehem (Stomal Therapy Nurse)	Geoff Haar (IBD Pharmacist)	Samantha McCall (IBD Clinical Nurse Consultant)	
Robert Bryant (Gastroenterologist)	Emma Halmos (Senior Gastrointestinal Dietitian)		
Britt Christensen (Gastroenterologist)	Heidi Harris (IBD Clinical Nurse Consultant)		
Rosemary Clerehan (Educational Linguist)			

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Level 1, 517 Flinders Lane Melbourne VIC 3000 | Phone: 1300 766 176 | email: gesa@gesa.org.au | Website: <http://www.gesa.org.au>

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