



Ozanimod

This information is for people with [Ulcerative Colitis](#) who are taking ozanimod (Zeposia). It is also for anyone who is thinking about starting treatment with ozanimod. This information can help you decide if ozanimod is right for you. It looks at:

- How ozanimod works.
- What you can expect from ozanimod treatment.
- Possible side effects.
- Stopping or changing treatment.

This information is about ozanimod in general. It should not replace advice from your IBD team.

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Key facts about ozanimod

- Ozanimod is a tablet, taken once a day.
- Ozanimod is used to treat Ulcerative Colitis. It may be used if other medicines have not worked well to control your symptoms.
- Ozanimod should not be used if you are pregnant, planning to become pregnant, or breastfeeding.
- Ozanimod can affect the way your immune system works. This means your body may not be able to fight off infections as well. Your IBD team will discuss this with you in more detail. If you have any concerns about infections, let your IBD team know.



Other names for ozanimod

Ozanimod is also known by the brand name Zeposia.

How ozanimod works

Ozanimod is a type of medicine called a sphingosine-1-phosphate (S1P) receptor modulator. Ozanimod attaches to a protein on some white blood cells (lymphocytes). Ozanimod stops lymphocytes from travelling around your body and causing inflammation in your gut. This reduces the symptoms of Colitis.

Why you might be offered ozanimod

Ozanimod is used to treat adults with [moderately to severely active Ulcerative Colitis](#). The aim of treatment is to get your Colitis under control and keep it under control.

Ozanimod can only be prescribed by a specialist in a hospital. Your IBD team may suggest ozanimod if you:

- Cannot have standard treatments or [biologic medicines](#)
- Did not respond well enough to standard treatments or biologic medicines
- Have stopped responding to standard treatments or biologic medicines

Standard treatments include [aminosalicylates \(5-ASAs\)](#), oral [steroids](#) or immunosuppressants (for example [azathioprine](#), [mercaptopurine](#) or [methotrexate](#)).



Deciding which medicine to take

Your IBD team might give you a choice of different treatments. You should consider the possible benefits, risks and the goals of your treatment. This will help you make an informed decision. You may want to think about:

- How you will take it.
- How it will fit in with your daily routine and lifestyle.
- How well it works.
- How quickly it is likely to work.
- Side effects you might experience.
- Whether you need ongoing tests or checks.
- Other medicines you are taking.
- If you are planning to get pregnant or breastfeed in the next few years.

Our [appointment guide](#) has a list of questions you might want to ask. It can help you focus on what matters most to you. You might find our information about other [medicines](#) and [surgery for Colitis](#) helpful too.

How well does ozanimod work in Colitis?

Find out more about how we [talk about the effectiveness of medicines](#).

Ozanimod is used to get and keep your Colitis symptoms under control (remission). Ozanimod does not work for everyone. But it can be helpful for some people if other treatments have not worked well.

A clinical trial looked at how effective ozanimod is. The trial included adults with moderate to severely active Colitis. The people in the trial were given either ozanimod or a placebo. A placebo is a dummy treatment that looks the same but does not have any medicine in it.



The table below shows how many people were in remission after taking ozanimod or a placebo after a year.

After one year of treatment...

	People not taking ozanimod (placebo)	People taking ozanimod
People with their Colitis under control (in remission)	 19%	 37%
People with some improvement in their Colitis (but not in remission)	 22%	 23%
People whose Colitis did not improve	 59%	 40%

Nearly twice as many people were in remission after taking ozanimod when compared to the people taking a placebo. But ozanimod did not work for everyone.

How long does ozanimod take to work?

Everyone responds differently to a new medicine. Some people start to feel better after taking ozanimod for about 10 weeks, but it may take longer.

How to take ozanimod

Ozanimod comes as a tablet that you take once per day. You should swallow the tablet whole. Do not split, crush or chew the tablet because it could change how much medicine gets into your body. Ozanimod can be taken with or without food.

What is the normal dose?

When you start taking ozanimod, you will take a low dose and gradually build up to the normal dose. This is to reduce some side effects such as a low heart rate.



To gradually build up to the normal dose, you will be given a 'treatment induction pack.' This is a pre-prepared pack with labelled tablets that you will take for the first seven days.

It has:

- Four tablets for days 1 to 4, taking one a day. These have a lower dose of ozanimod.
- Three tablets for days 5 to 7, taking one a day. These have a slightly higher dose to get your body used to taking ozanimod.

You should then have finished the induction pack of tablets.

On day eight of treatment, you will start taking tablets from a 'maintenance pack.' This pack has tablets containing the normal dose of ozanimod. From day eight onwards, you will take one of these tablets each day.

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Continue taking every day
One 0.23mg tablet	One 0.23mg tablet	One 0.23mg tablet	One 0.23mg tablet	One 0.46mg tablet	One 0.46mg tablet	One 0.46mg tablet	One 0.92mg tablet	One 0.92mg tablet

Let your IBD team know if you forget to take a dose of ozanimod or miss a dose during your first 14 days of treatment. You may need to start the treatment induction pack again.

How long will you take ozanimod for?

You are likely to have a planned course of treatment for one year. After that, your treatment plan may be extended. Your IBD team will continue to check that ozanimod is still working well for you.



Stopping or changing treatment

There are a few reasons why you or your IBD team might think about stopping or changing your treatment:

- **You have side effects**

If you have side effects that are serious or hard to manage, stopping ozanimod might be the best option for you.

- **Ozanimod hasn't worked**

You will have regular checks to see if your Colitis is improving and ozanimod is working for you. If it is not working well, your IBD team might suggest stopping ozanimod and trying a different treatment.

You should not stop taking ozanimod without informing your IBD team.

Taking ozanimod with other medicines for Colitis

Your IBD team will let you know if you need to take other medicines for your Colitis. You may have to start or continue to take [steroids](#) or [5-ASAs](#) alongside ozanimod.

Because ozanimod can affect your immune system, it should not be taken with other immunosuppressants such as [azathioprine and mercaptopurine](#).

Clinical trials have not looked at whether it is safe to take ozanimod alongside [biologic medicines](#).



Checks before starting treatment

When discussing ozanimod, tell your IBD team if you:

- Have previously taken any other medicines to treat your Colitis.
- Have had a heart attack or stroke in the last six months.
- Have an irregular or abnormal heartbeat.
- Have a severe infection such as hepatitis or tuberculosis.
- Are pregnant or are not using effective contraception.

Before you start taking ozanimod, your IBD team may offer some tests to check that it is the right treatment for you. They are likely to:

- Check if you've ever had chicken pox, shingles, TB, cold sores or genital herpes
- Take blood tests to check for hepatitis viruses, the chicken pox or shingles virus, and HIV
- Do a chest X-ray and blood test to check for TB
- Find out if all your vaccinations are up-to-date
- Do a Full Blood Count (FBC). This is a blood test that checks your levels of red and white blood cells and platelets
- Do a blood test to check how well your liver is working
- If you are fertile and sexually active, check you have had a negative pregnancy test

Some other checks you might need are:

Heart monitoring

Ozanimod can cause a slow heart rate in some people. Before you start taking ozanimod, you will have your heart checked. This is done using a test called an electrocardiogram (ECG).

If you have a slow heart rate or certain heart conditions, your doctor will also monitor you for at least six hours after your first dose of ozanimod, checking your pulse and blood



pressure every hour. You may also need an ECG six hours after you have taken ozanimod.

Eye checks

An uncommon side effect of ozanimod is blurred vision. If you have diabetes or a history of eye problems such as uveitis, you may need to have an eye examination before starting ozanimod.

Ongoing checks

While taking ozanimod, your IBD team will check how well it is working.

You will have:

- Regular blood tests to check for signs of infection and check your levels of red and white blood cells
- Liver function tests every three months
- Regular blood pressure checks

Your IBD team will let you know when these checks are needed. They will also ask about your Colitis symptoms and any side effects that you are getting.

Special precautions

Ozanimod may increase your risk of skin cancer. You should protect your skin from the sun by wearing protective clothing. Applying sunscreen regularly and staying in the shade can also protect your skin. Visit the NHS website for [tips on staying safe in the sun](#).

Side effects

All medicines can have side effects, although not everyone will get them. Some side effects can happen right away, others may happen later. Some can even last for a short time after you stop treatment.



Some side effects are mild and may go away on their own or after you stop taking ozanimod. Others may be more serious and could need treatment. Some side effects might mean that ozanimod is not right for you.

Possible serious side effects

Some serious side effects may need urgent treatment. Tell your GP or IBD team if you get any of the following side effects:

Infections

Ozanimod affects your immune system. This means that while you are taking ozanimod, your body may get infections more easily. You might get more infections than you used to. Or they might last longer or be more serious than usual.

More than 1 in 10 people taking ozanimod may get an infection of their nose or nostrils, mouth or throat. Up to 1 in 10 people taking ozanimod may get a urinary tract infection (UTI).

If you think you have an infection, contact your GP for treatment and let your IBD team know.

Some symptoms of infection to look out for include:

- A high temperature, fever or chills
- Sore throat, stuffy or runny nose
- A cough that will not go away
- Shortness of breath
- Unexplained tiredness
- Pain or a burning sensation when peeing
- Needing to pee more than usual

If you have an infection, your doctor may ask you to stop taking ozanimod until you feel better.



Liver damage

Up to 1 in every 1000 people may be affected by liver damage while they are taking ozanimod. If you develop any of the following symptoms while you are taking ozanimod, speak to your GP or IBD team straight away:

- Feeling sick or being sick
- Pain on the right side of your tummy
- Tiredness
- Loss of appetite,
- Yellowing of your skin or the whites of your eyes
- Darker pee than is normal for you

Other side effects

Very common: may affect more than 1 in 10 people taking ozanimod

- Low level of a type of white blood cell called lymphocytes. This means your body might not be able to fight off infections as well. This is usually mild and will resolve itself.

Common: may affect between 1 in 10 and 1 in 100 people taking ozanimod

- Slow heart rate
- Increase in blood pressure
- Inflammation of the throat (pharyngitis)
- Infection of your lungs
- Shingles
- Cold sores
- Headache
- Drop in blood pressure
- Swelling of your ankles and feet, due to fluid retention (peripheral oedema)
- Increased liver enzyme levels in blood tests (a sign of liver problems)
- Lung problems which can cause breathlessness



Uncommon: may affect between 1 in 100 and 1 in 1000 people taking ozanimod

- Blurred vision (macular oedema)
- Itchy rash or hives (urticaria)
- Allergic reaction

Rare: may affect between 1 in 1000 and 1 in 10000 people taking ozanimod

- A brain infection called progressive multifocal leukoencephalopathy (PML)

Allergic reaction

The signs and symptoms of a medicine allergy usually occur soon after taking the medicine. But serious allergic reactions are uncommon. Up to 1 in every 100 people taking ozanimod may have an allergic reaction.

Call 999 or emergency medical help if you think you are having a severe allergic reaction.

Signs to look out for include:

- Difficulty breathing or swallowing
- Feeling extremely dizzy or light-headed
- Swelling of your face, lips, mouth or throat
- A rash or raised, itchy patches on your skin (hives)

The patient information leaflet (PIL) that comes with your medicine also has a full list of potential side effects. You can also download the leaflet online from [medicines.org.uk](https://www.medicines.org.uk).

Let your IBD team know if you get any side effects while taking ozanimod.

We encourage you to report any side effects to the Medicines and Healthcare Products Regulatory Agency (MHRA) through the Yellow Card scheme. Your doctor should also report it. Report your side effect at yellowcard.mhra.gov.uk.



Taking other medicines

Tell your doctor, IBD team or pharmacist about any other medicines you are taking or thinking of taking. This includes:

- Over-the-counter medicines, such as cold or flu medicines
- Multi-vitamins or supplements
- Herbal, complementary or alternative therapies.

Some medicines can affect the way ozanimod works.

Before taking ozanimod, tell your doctor or pharmacist if you are taking, or have recently taken, any of the following medicines:

- Other medicines used to treat Colitis, such as [azathioprine and mercaptopurine](#).
- Medicines which suppress or modulate your immune system.
- Medicines used to treat MS such as alemtuzumab, beta interferon, dimethyl fumarate, glatiramer acetate, mitoxantrone, natalizumab or teriflunomide.
- Gemfibrozil, a medicine used to reduce levels of fats or cholesterol in the blood.
- Clopidogrel, a medicine used to prevent blood clots.
- Rifampicin, an antibiotic for treating tuberculosis and other serious infections.
- Medicines called monoamine oxidase inhibitors for treating depression or Parkinson's disease.
- Medicines that slow your heart rate such as beta blockers or calcium channel blockers.



Vaccinations

Your IBD team will check that your vaccinations are up to date before you start treatment with ozanimod. This may include the shingles vaccine, chickenpox vaccine and BCG.

- You should not have live vaccines while taking ozanimod.
- If you have had a live vaccine, you should wait at least one month before starting ozanimod.
- You should also avoid live vaccines for three months after stopping ozanimod.

Live vaccines used in the UK include:

- TB vaccine
- Shingles vaccine – but a non-live version is also available
- Chickenpox vaccine
- Measles, mumps and rubella vaccines
- Nasal flu vaccine used in children – but the injected flu vaccine used in adults is **not** live
- Rotavirus vaccine
- Yellow fever vaccine
- Oral typhoid vaccine – but the injected typhoid vaccine is **not** live

If anyone in your family or household is due to have a live vaccine, check with your IBD team whether you need to take any special precautions.

The flu, pneumococcal and COVID-19 vaccines are not live vaccines and are safe to have while you are taking ozanimod.



Pregnancy and fertility

Let your IBD team know immediately if you are taking ozanimod and you become pregnant or you think you might be pregnant. They will be able to discuss the next steps with you.

You should not use ozanimod if you are pregnant or breastfeeding. 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.
- If you are fertile and sexually active, you must have a negative pregnancy test before starting ozanimod. This may be repeated throughout your treatment.
- You must use effective contraception while taking ozanimod and for 3 months after you stop taking ozanimod.

If you are planning to get pregnant, speak with your IBD team as soon as possible. You should stop taking ozanimod 3 months before planning a pregnancy. This will allow time to review your treatment options and make sure your Colitis is controlled as well as possible.

There has not been any research into whether ozanimod affects male or female fertility in humans yet. In studies with animals, ozanimod was not found to have any effect on fertility.

Read our information on [pregnancy](#) and [reproductive health](#).

Breastfeeding

Ozanimod can pass into breast milk. It is not yet known how this could affect your baby. You should not take ozanimod if you are breastfeeding.



Read our information on [pregnancy and breastfeeding](#).

Drinking alcohol

Alcohol is not known to interact with ozanimod. Ask your IBD team about drinking alcohol while taking ozanimod. To keep the health risks from drinking alcohol low it is best to stay within the [recommended limits](#).

Who to talk to if you are worried

Taking medicines and managing side effects can be difficult – we understand and we're here to help. Our [Helpline](#) can answer general questions about treatment options and can help you find support from others with the conditions.

Your IBD team are also there to help. You can talk to them about your dosage, how they'll be monitoring you and what alternatives may be available. You should also get in touch with your IBD team if you have any new symptoms or side effects.

It can take time to find the medicine that's right for you. Don't be afraid to ask questions and seek out extra support when you need it.

This information is general and doesn't replace specific advice from your health professional. Talk to your doctor or IBD team for more information.

Help and support from Crohn's & Colitis UK

We're here for you whenever you need us. Our award-winning information on Crohn's Disease, Ulcerative Colitis, and other forms of Inflammatory Bowel Disease have the information you need to help you manage your condition.

We have information on a wide range of topics, from individual medicines to coping with symptoms and concerns about relationships and employment. We'll help you find answers, access support and take control.

All information is available on our website: crohnsandcolitis.org.uk/information



Our Helpline is a confidential service providing information and support to anyone affected by Crohn's or Colitis.

Our team can:

- Help you understand more about Crohn's and Colitis, diagnosis and treatment options
- Provide information to help you live well with your condition
- Help you understand and access disability benefits
- Be there to listen if you need someone to talk to
- Help you to find support from others living with the condition

Call us on 0300 222 5700 or email helpline@crohnsandcolitis.org.uk.

See our website for LiveChat: crohnsandcolitis.org.uk/livechat.

Crohn's & Colitis UK Forum

This closed-group community on Facebook is for everyone affected by Crohn's or Colitis.

You can share your experiences and receive support from others at:

facebook.com/groups/CCUKforum.

Help with toilet access when out

Members of Crohn's & Colitis UK get benefits including a Can't Wait Card and a RADAR key to unlock accessible toilets. This card shows that you have a medical condition, and will help when you need urgent access to the toilet when you are out. See

crohnsandcolitis.org.uk/membership for more information, or call the Membership Team on 01727 734465.

About Crohn's & Colitis UK

We are Crohn's & Colitis UK, a national charity fighting for improved lives today – and a world free from Crohn's and Colitis tomorrow. To improve diagnosis and treatment, and to fund research into a cure; to raise awareness and to give people hope, comfort and



confidence to live freer, fuller lives. We're here for everyone affected by Crohn's and Colitis.

This information is available for free thanks to the generosity of our supporters and members. Find out how you can join the fight against Crohn's and Colitis: call **01727 734465** or visit crohnsandcolitis.org.uk.

About our information

Crohn's & Colitis UK information is research-based and produced with patients, medical advisers and other professionals. They are prepared as general information and are not intended to replace advice from your own doctor or other professional. We do not endorse any products mentioned.

We hope that you've found this information helpful. You can email the Knowledge and Information Team at evidence@crohnsandcolitis.org.uk if:

- You have any comments or suggestions for improvements
- You would like more information about the research on which the information is based
- You would like details of any conflicts of interest

You can also write to us at **Crohn's & Colitis UK, 1 Bishops Square, Hatfield, Herts, AL10 9NE** or contact us through the **Helpline: 0300 222 5700**.

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Ozanimod, edition 1a

Last review: February 2023

Latest amendment: November 2024

Next review: February 2026

