



A guide for people with ulcerative colitis taking ZEPOSIA

INTRODUCTION

You are receiving this booklet as you have been prescribed ZEPOSIA by your doctor. ZEPOSIA is used for the treatment of ulcerative colitis (UC) in adults.

While this guide can help you understand ZEPOSIA and what to expect from your treatment, for medical advice or further information, please speak to your doctor or nurse.

Scan the QR code to learn more about ZEPOSIA and UC, or visit www.gastro-hub.com.au/patient



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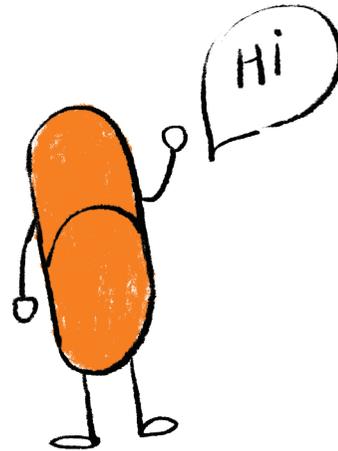


ABOUT ZEPOSIA

What is ZEPOSIA?

ZEPOSIA is an oral medication used to treat adults with moderate to severely active UC.

ZEPOSIA contains an active substance called ozanimod, which belongs to a group of medicines called sphingosine 1-phosphate (S1P) receptor modulators.



How does ZEPOSIA work?

UC is an inflammatory disease of the colon (large intestine and rectum).

The exact cause of UC is unknown, but it is believed to be related to a problem with the immune response. In UC, the immune system responds incorrectly and moves white blood cells (a type of immune cell) to the colon. This leads to ongoing inflammation that damages the colon and causes UC symptoms.

ZEPOSIA can affect the ability of some white blood cells to move freely around the body. This stops the cells from reaching the lining of the colon where they may cause inflammation and damage.

ZEPOSIA is used to treat adult patients with moderately to severely active UC. If you have UC, you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, your doctor may give you ZEPOSIA to reduce the signs and symptoms of your disease.

ZEPOSIA may be used together with other medicines, such as corticosteroids and aminosalicylates, to treat UC. Your doctor will tell you which of these other medicines you should use.

Getting started with ZEPOSIA

Before you get started on ZEPOSIA, your doctor will perform a number of tests.



Electrocardiogram (ECG): this measures and records the heart's rhythm and activity to check for any abnormalities.



Blood tests: your doctor will conduct blood tests to check your liver function and blood cell counts.



Eye assessment: your doctor will arrange an eye assessment for you if you have risk factors for macular oedema (a condition that causes problems with your vision or other symptoms of swelling in the central vision area at the back of the eye). Examples of risk factors include if you have diabetes mellitus, a history of uveitis, or a history of retinal disease. Tell your doctor if you have had any problems with your vision.



Pregnancy test: ZEPOSIA cannot be used while you are pregnant or breastfeeding. If you are a woman who is able to become pregnant, a negative pregnancy test will be required before you begin treatment.



Active infections: your doctor will check to make sure you do not have any active infections before you begin treatment. If you do, your doctor will delay treatment.



Assess current or prior medications: it is important you tell your doctor about any other medicines you are taking, including those you can buy from a pharmacy or health food shop without a prescription.



Vaccinations: your doctor will check if you are protected against chickenpox or 'varicella zoster virus' before you start taking ZEPOSIA. You may need to have the varicella vaccination at least 1 month before you begin taking ZEPOSIA. Some vaccines (called 'live attenuated vaccines') should not be given whilst taking ZEPOSIA and for 3 months after stopping treatment with ZEPOSIA. Your doctor will check if you should have any vaccines before you receive ZEPOSIA.

HOW TO TAKE ZEPOSIA

Dose initiation

You will start your treatment with ZEPOSIA using the 'initiation pack'. The treatment in the initiation pack starts with a lower dose and this is gradually increased over the first 7 days of treatment. This is to minimise the risk of heart rate reductions.

On Days 1 to 4 you will take one light grey capsule (230 microgram) once a day. On days 5 to 7, you will take one light grey and orange capsule (460 microgram) once a day.

Take one capsule per day as indicated on the initiation pack.

Regular dosing regimen

On Day 8 and thereafter, once you have completed the 'initiation pack', you will move on to a 'maintenance pack' with orange capsules each containing the recommended dose of 920 microgram of ZEPOSIA.

You will continue regular treatment with one 920 microgram capsule daily.

Follow all directions given to you by your doctor carefully. If you are unsure, ask your doctor or pharmacist for help.

How do I take it?

Tick off each day once you have taken your capsule

First treatment week:

<input type="checkbox"/> DAY 1 Date:	<input type="checkbox"/> DAY 2 Date:	<input type="checkbox"/> DAY 3 Date:	<input type="checkbox"/> DAY 4 Date:
 230 microgram	 230 microgram	 230 microgram	 230 microgram
<input type="checkbox"/> DAY 5 Date:	<input type="checkbox"/> DAY 6 Date:	<input type="checkbox"/> DAY 7 Date:	
 460 microgram	 460 microgram	 460 microgram	

Second treatment week:

<input type="checkbox"/> DAY 8 Date:	<input type="checkbox"/> DAY 9 Date:	<input type="checkbox"/> DAY 10 Date:	<input type="checkbox"/> DAY 11 Date:
 920 microgram	 920 microgram	 920 microgram	 920 microgram
<input type="checkbox"/> DAY 12 Date:	<input type="checkbox"/> DAY 13 Date:	<input type="checkbox"/> DAY 14 Date:	
 920 microgram	 920 microgram	 920 microgram	

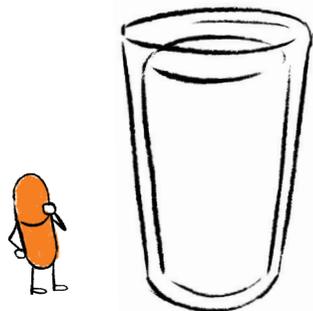
FREQUENTLY ASKED QUESTIONS

How should I take ZEPOSIA?

Swallow the capsule whole with a full glass of water, once a day.

ZEPOSIA can be taken with or without food.

Take your medicine at about the same time each day.



How long do I take ZEPOSIA for?

Continue taking ZEPOSIA until your doctor asks you to stop.

Do not stop taking ZEPOSIA without talking to your doctor.

What do I do if I miss a dose?

During the first 14 days of treatment

If you have missed a dose of ZEPOSIA on one day, contact your doctor before you take the next dose.

Your doctor will need to prescribe a new initiation pack and you will have to restart at Day 1.



After 14 days of consecutive treatment

If you miss a dose, take a tablet as soon as possible on the same day. However, if it is nearly time for your next dose, skip the missed dose. Then take the next dose at your usual time.

Do not take a double-dose to make up for a forgotten dose.

If you stop taking ZEPOSIA for more than 7 consecutive days between Day 15 and 28 of treatment or more than 14 consecutive days after Day 28 of treatment, you will need to start the treatment 'initiation pack' again.

If you are not sure what to do or need advice about taking ZEPOSIA, ask your doctor or pharmacist.

What do I do if I want to stop ZEPOSIA?

Do not stop taking ZEPOSIA without talking to your doctor first.

Your doctor will tell you if you need to stop taking ZEPOSIA. Your symptoms may return or become worse if you stop ZEPOSIA. Tell your doctor straight away if your symptoms become worse after you have stopped ZEPOSIA.

If you stop taking ZEPOSIA for more than 7 consecutive days between day 15 and 28 of treatment or more than 14 consecutive days after day 28 of treatment, you will need to re-start treatment with the 'initiation pack'.

If you have stopped taking ZEPOSIA, it is important to tell any doctors or pharmacists involved in your treatment that you used to take ZEPOSIA, for 3 months after you have stopped. This is because ZEPOSIA can stay in your body for up to 3 months after you stop taking it. Your white blood cell count (lymphocyte count) may also remain low during this time and the side effects described in this booklet may still occur.

What if I take too much ZEPOSIA?

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much ZEPOSIA. Take the medicine pack with you.

Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

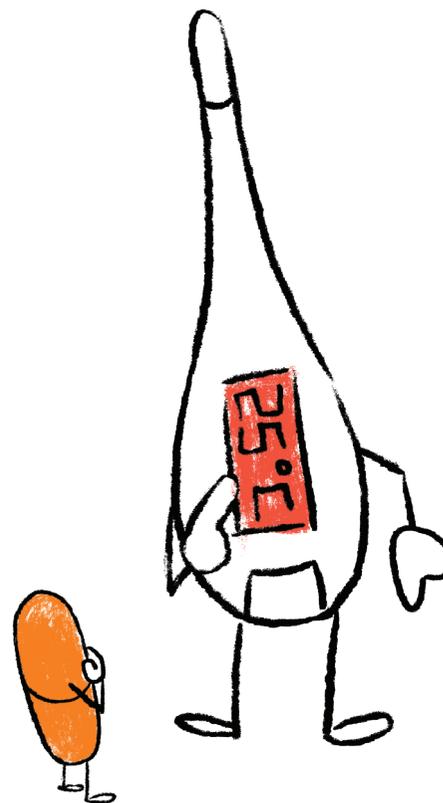
How do I store ZEPOSIA?

Store the capsules in their original package, in a cool dry place where the temperature stays below 25°C.

Store ZEPOSIA in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- > in the bathroom or near a sink, or
- > in the car or on window sills.

Keep it where young children cannot reach it.



SIDE EFFECTS

Like all medicines, ZEPOSIA can have side effects. If you do experience any side effects, most of them will be minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Speak to your doctor if you have any of these side effects and they worry you:

Very common side effects include:

- › infections of the nose or nostrils, nasal cavity, mouth, throat (pharynx), or voice box (larynx) caused by viruses
- › low blood levels of a type of white blood cell — called lymphocytes

Common side effects include:

- › sore throat (pharyngitis)
- › respiratory (lung) infection
- › herpes simplex (cold sores)
- › headache
- › swelling of arms, hands, feet, ankles or legs due to fluid build-up

Tell your doctor or pharmacist as soon as possible if your symptoms worsen or if you notice anything else that may be making you feel unwell while you are taking ZEPOSIA.



Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects:

- › low heart rate
- › urinary tract infection
- › increase in blood pressure
- › low blood pressure when you stand up from sitting or lying down (orthostatic hypotension)
- › allergic reaction – the signs may include rash or hives, swelling of the face, lips, mouth, tongue or throat, shortness of breath, wheezing or difficulty breathing
- › signs of serious infections such as fever, sore throat, cough, tiredness, aching joints and/or muscles
- › new or worsening breathing problems
- › significant changes in vision, including shadows or blind spots in the centre of your vision, blurred vision, or problems seeing colours or details
- › increased liver enzyme levels in blood tests or yellowing of the skin, mucus membrane or eyes (jaundice)
- › rash of small fluid-filled blisters, appearing on reddened skin, signs of viral infection that can be potentially severe (herpes zoster or shingles)
- › signs of brain infection (progressive multifocal leukoencephalopathy) – signs may include worsening of your symptoms as well as any new or unfamiliar symptoms
- › symptoms of fungal infection in the brain, such as headache, fever, neck pain, nausea and/or vomiting, sensitivity to light, confusion or others noticing changes in your behaviour
- › a severe headache, feeling confused, or having seizures and vision loss.

Other side effects not listed here may occur in some people.

WHILST TAKING ZEPOSIA

Things you should do:

- › Remind any doctor, dentist or pharmacist you visit that you are using ZEPOSIA.
- › Keep all of your doctor's appointments so that your progress can be checked. Your doctor will do tests from time to time to ensure that the medicine is working and to prevent unwanted side effects.
- › Tell your doctor if you plan to receive a vaccine.
- › Avoid becoming pregnant while taking ZEPOSIA or in the 3 months after you stop taking it.
- › While you are taking ZEPOSIA (and for up to 3 months after you stop taking it), you may get infections more easily. Any infection that you already have may get worse.
- › Limit your exposure to sunlight and UV light. There may be an increased risk of skin cancer with medicines like ZEPOSIA. You should limit your exposure to sunlight by wearing protective clothing and regularly applying sunscreen. Tell your doctor if you are receiving phototherapy.

Call your doctor straight away if you:

- › Notice or others notice worsening of your symptoms as well as any new or unfamiliar symptoms.
- › Develop a headache, fever, neck pain, nausea and/or vomiting, sensitivity to light, confusion or others notice changes in your behaviour.
- › Get a severe headache, feel confused, or have seizures and vision loss.

Things you should not do:

- › Do not stop using this medicine without talking to your doctor.



PREGNANCY AND ZEPOSIA

- › Tell your doctor if you are or may be pregnant or plan to become pregnant. You should avoid becoming pregnant whilst taking ZEPOSIA or in the three months after you stop taking it, because there is a risk of harm to your unborn baby.
- › Tell your doctor if you are breastfeeding. You should not breastfeed whilst taking ZEPOSIA, as it is not known if ZEPOSIA passes into breastmilk.
- › If you are a woman who could become pregnant during treatment, your doctor will ask to have a pregnancy test to confirm you are not pregnant before taking ZEPOSIA.
- › If you are a woman who could become pregnant during treatment, you should use an effective method of contraception while you are taking ZEPOSIA, and for 3 months after stopping ZEPOSIA.
- › Please speak to your doctor about reliable forms of contraception.
- › If you become pregnant while taking ZEPOSIA, tell your doctor without delay. You and your doctor will decide what is best for you and your baby.



RESOURCES AND SUPPORT

There is a huge amount of information about UC available. You may also want to join a support group to speak to others who are in the same situation, or to find out more information about your condition.



ZEPOSIA patient site

www.gastro-hub.com.au/patient

The code to access the ZEPOSIA patient website is the last 4 digits of the barcode on your ZEPOSIA pack.



Additional resources and support

For general support and information about UC, you may want to contact the following organisations.

Crohn's & Colitis Australia

Encourages people to live fearlessly with their condition, while supporting research to search for a cure. It offers support, advocacy and a helpline.

www.crohnsandcolitis.org.au

1800 138 029

IBD Support Australia

Provides a support network for people with inflammatory bowel diseases, including UC, through an online forum and other resources.

www.ibd.org.au

Gastroenterological Society of Australia (GESA)

GESA has patient information on UC, including resources on diet and various medications.

www.gesa.org.au

The Gut Foundation

Has online resources and information available free and for purchase, covering a range of gut issues, including UC.

www.gutfoundation.com.au

Health Direct

This government website offers information and links about UC, and information about medication.

www.healthdirect.gov.au/ulcerative-colitis

USEFUL CONTACTS

You can use this space to write down any key contacts you may need during your UC treatment.

Gastroenterologist:

GP:

Other healthcare professionals:

Local support organisations:



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