ZEPOSIA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using ZEPOSIA?

ZEPOSIA contains the active ingredient ozanimod. ZEPOSIA is used to treat multiple sclerosis and ulcerative colitis in adults.
For more information, see Section 1. Why am I using ZEPOSIA? in the full CMI.

2. What should I know before I use ZEPOSIA?

Do not use if you have ever had an allergic reaction to ozanimod or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, recently had or are planning to have a vaccination, take any other medicines or receive phototherapy, or are pregnant or plan to become pregnant or are breastfeeding. You should avoid becoming pregnant while taking ZEPOSIA or in the 3 months after you stop taking it.

For more information, see Section 2. What should I know before I use ZEPOSIA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZEPOSIA and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ZEPOSIA?

You start your ZEPOSIA treatment with an initiation pack that lasts for 7 days. The initiation pack contains lower doses of ZEPOSIA that increase gradually over the first 7 days of treatment.

On Day 8 and thereafter you will take one 920 microgram capsule daily. If you have mild or moderate chronic liver problems, your doctor may need to reduce your 'maintenance' dose to one 920 microgram capsule every other day.

More instructions can be found in Section 4. How do I use ZEPOSIA? in the full CMI.

5. What should I know while using 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. • Limit your exposure to sunlight and UV light.
Things you should not do	• Do not stop using this medicine without talking to your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ZEPOSIA affects you. • This medicine is not likely to affect you being able to drive, cycle or use any tools or machines.
Looking after your medicine	• Store the capsules in the original package. • Store in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using ZEPOSIA? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.
Common side effects include: viral infections of the nose, mouth, throat, or voice box; low blood levels of a type of white blood cell; sore throat; lung infection; cold sores; headache; swelling of arms, hands, feet, ankles or legs.
Serious side effects include: low heart rate; allergic reaction; changes in blood pressure; serious infections (e.g. urinary, shingles, brain infection); new or worsening breathing problems; significant changes in visions; increased liver enzyme levels in blood tests or yellow pigmentation of the skin, mucus membrane or eyes.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ZEPOSIA

Active ingredient(s): *ozanimod*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZEPOSIA. **You should speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZEPOSIA.**

Where to find information in this leaflet:

1. Why am I using ZEPOSIA?

ZEPOSIA contains the active ingredient ozanimod. Ozanimod belongs to a group of medicines called sphingosine 1-phosphate (S1P) receptor modulators.

ZEPOSIA can affect the ability of some white blood cells to move freely within the body and stops them from reaching the central nervous system (the brain, spine and optic nerves) and the intestinal lining, where they can cause inflammation and damage.

Multiple Sclerosis

Multiple Sclerosis (MS) is a disease in which inflammation in the body attacks and destroys the protective coating around your nerves (called myelin) in the central nervous system. This stops the nerves from working properly. The symptoms of MS can vary from person to person.

ZEPOSIA is used to treat adult patients with relapsing forms of multiple sclerosis.

In relapsing MS, patients will experience relapse or flare-ups from time to time, followed by a period of recovery and stability, where symptoms may disappear or some symptoms may remain.

ZEPOSIA helps to reduce inflammation and may protect against attacks on the nerves in the central nervous system. In doing so, ZEPOSIA can help reduce the number of relapses and slow down the progression of disability.

Ulcerative Colitis

Ulcerative colitis (UC) is an inflammatory disease of the bowel.

ZEPOSIA is used to treat adult patients with moderately to severely active ulcerative colitis. 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.

2. What should I know before I use ZEPOSIA?

Warnings

Do not use ZEPOSIA if:

1. you are allergic to ozanimod, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
2. you have had a heart attack, angina, stroke or warning of a stroke or certain types of heart failure in the last 6 months
3. you have certain types of irregular or abnormal heartbeats (arrhythmia)
4. you have untreated severe breathing problems when you sleep (severe sleep apnoea)

Before you start taking ZEPOSIA, your doctor will conduct liver and blood tests. You will also have an electrocardiogram (also called an ECG), which measures and records the heart's rhythm and activity.

Tell your doctor if you:

- have a slow heart rate
- have high blood pressure
- have problems with your liver
- have an infection - 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.
- are taking or have taken any medicines that affect the immune system or other medicines used to treat MS or UC (see "Taking other medicines"). Taking ZEPOSIA with these medicines may increase the risk of infection.
- have worsening of your symptoms or any new or unfamiliar symptoms or if others notice worsening of your symptoms or new or unfamiliar symptoms. These may be due to a rare infection of the brain called 'Progressive Multifocal Leukoencephalopathy' (PML), which has been reported in patients receiving medicine for MS and UC.
  If you are taking ZEPOSIA for MS and PML is confirmed, your doctor will stop treatment with Zeposia. However, some people may get a reaction

when Zeposia is removed. This reaction (known as IRIS or immune reconstitution inflammatory syndrome) may lead to your condition getting worse, including worsening of brain function.
- have a headache, fever, neck pain, nausea and/or vomiting, sensitivity to light, confusion or others notice changes in your behaviour. These symptoms may be due to a type of fungal (cryptococcal) infection in the brain.
- have low levels of a type of white blood cell - called lymphocytes
- have never had, or are not sure if you have had chickenpox or you have not been vaccinated against varicella zoster virus (VZV). Your doctor can do a blood test to check if you need VZV vaccination.
- recently had or are planning to have a vaccination. 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.
- have problems with your vision or other symptoms of swelling in the central vision area at the back of the eye (a condition called macular oedema)
- have inflammation of the eye (uveitis), diabetes (which can cause problems with your eyes) or history of problems with your retina (the thin layer of tissue on the inside wall at the back of the eye). These may increase your risk of macular oedema. Your doctor will organise an eye examination before you start ZEPOSIA and follow up examinations whilst you are on ZEPOSIA.
- get a severe headache, feel confused, or have seizures and vision loss during treatment with ZEPOSIA. These symptoms may be due to a syndrome called 'Posterior Reversible Encephalopathy Syndrome' (PRES).

Limit your exposure to sunlight and UV light

There may be an increased risk of skin cancer with medicines such as ZEPOSIA. You should limit your exposure to sunlight and UV light, by wearing protective clothing and applying regular sunscreen (with high sun protection factor). Tell your doctor if you are receiving phototherapy with UV-B radiation or PUVA-photochemotherapy as they should not be used with ZEPOSIA.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

You should avoid becoming pregnant while taking ZEPOSIA or in the 3 months after you stop taking it, because there is a risk of harm to your unborn baby.

You should have a pregnancy test to confirm that you are not pregnant before starting ZEPOSIA and you should use an effective method of contraception during treatment and for 3 months after stopping ZEPOSIA.

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.

Talk to your doctor if you are breastfeeding. You should not breastfeed while taking ZEPOSIA. This is because it is not known if this medicine passes into human milk.

Use in children or adolescents

Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness of ZEPOSIA in children younger than 18 years have not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

- medicines that suppress or modulate the immune system (e.g. ciclosporin, eltrombopag, azathioprine), including other medicines used to treat MS or UC
- gemfibrozil for fats or cholesterol in the blood
- clopidogrel to prevent blood clots
- rifampicin, an antibiotic for treating tuberculosis and other serious infections
- monoamine oxidase (MAO) inhibitors, such as phenelzine for depression or selegiline for Parkinson's disease
- medicines that slow your heart rate
- certain type of vaccines

These medicines may be affected by ZEPOSIA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZEPOSIA.

4. How do I use ZEPOSIA?

How much to take

- When you first start taking ZEPOSIA, you will receive an 'initiation pack' which contains the doses as listed in the table below.
- Take one capsule each day as indicated on the 'initiation pack'.
- Your treatment will start at a lower dose and will gradually be increased over the first 7 days of treatment. This is to minimise the risk of heart rate reductions.

Day	Daily Dose	Capsule Colour
Day 1 to 4	Take one 230 microgram capsule once a day	Light grey
Day 5 to 7	Take one 460 microgram capsule once a day	Light grey and orange

- 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.
- If you have mild or moderate chronic liver problems, your doctor may need to reduce your 'maintenance' dose to one 920 microgram capsule every other day.
- Follow the instructions provided and use ZEPOSIA until your doctor tells you to stop.

When to take ZEPOSIA

- Take ZEPOSIA at about the same time each day, or as directed by your doctor.

How to take ZEPOSIA

- Swallow the capsule whole with a full glass of water.
- ZEPOSIA can be taken with or without food.

If you forget to use ZEPOSIA

ZEPOSIA should be used regularly at the same time each day, or as directed by your doctor.

During the first 14 days of treatment

If you have missed a dose of ZEPOSIA, call 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 treatment for 14 consecutive days

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.

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

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 you have worsening of your symptoms 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 start the treatment 'initiation pack' again.

ZEPOSIA will 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 leaflet may still occur.

If you use too much ZEPOSIA

If you think that you have used too much ZEPOSIA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using 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.
- Limit your exposure to sunlight and UV light.
- Avoid becoming pregnant while taking ZEPOSIA or in the 3 months after you stop taking it.

Call your doctor straight away if you:

- get symptoms of fungal infection in the brain, such as 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZEPOSIA affects you.

This medicine is not likely to affect you being able to drive, cycle or use any tools or machines.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it 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.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are 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.

Serious side effects

Serious side effects	What to do
• 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 the vision, blurred vision, problems seeing colours or details • increased liver enzyme levels in blood tests or yellow pigmentation 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) - worsening of your symptoms as well as any new or unfamiliar symptoms	**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.**

Other side effects

Other side effects	What to do
Very common • 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	**Speak to your doctor if you have any of these side effects and they worry you.**
Common • 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 if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZEPOSIA contains

Active ingredient (main ingredient)	ZEPOSIA 230 microgram capsules: Each capsule contains 230 microgram of ozanimod (as hydrochloride). ZEPOSIA 460 microgram capsules: Each capsule contains 460 microgram of ozanimod (as hydrochloride). ZEPOSIA 920 microgram capsules: Each hard capsule contains 920 microgram of ozanimod (as hydrochloride).

Other ingredients **(inactive ingredients)**	Microcrystalline cellulose Silicon dioxide Croscarmellose sodium Magnesium stearate Capsule shells: Each 230 microgram capsule contains gelatin, titanium dioxide, yellow iron oxide, black iron oxide and red iron oxide. Each 460 microgram capsule contains gelatin, titanium dioxide, yellow iron oxide, black iron oxide and red iron oxide. Each 920 microgram capsule contains gelatin, titanium dioxide, yellow iron oxide and red iron oxide. The printing ink on the capsules is black ink.

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What ZEPOSIA looks like

ZEPOSIA 230 microgram capsule is light grey opaque imprinted in black ink with “OZA” on the cap and “0.23 mg” on the body.

ZEPOSIA 460 microgram capsule is light grey / orange opaque imprinted in black ink with “OZA” on the cap and “0.46 mg” on the body.

ZEPOSIA 920 microgram capsule is orange opaque imprinted in black ink with “OZA” on the cap and “0.92 mg” on the body.

Pack sizes

Treatment initiation pack is a wallet pack containing 7 capsules: 4 x 230 microgram capsules and 3 x 460 microgram capsules (AUST R 318801).

Maintenance pack containing 28 x 920 microgram capsules (AUST R 318800).

Who distributes ZEPOSIA

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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