

- ▼ This medicine is subject to additional monitoring in Australia. 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®

ozanimod

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zeposia. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zeposia against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Zeposia is used for

Zeposia is used to treat adult patients with Relapsing forms of Multiple Sclerosis. Zeposia contains an active substance called ozanimod, which belongs to a group of medicines called sphingosine-1-phosphate (S1P) receptor modulators.

Multiple Sclerosis (MS) is a disease in which inflammation in the body attacks and destroys the protective coating around your nerves (called myelin). This stops the nerves from working properly. The symptoms of MS can vary from person to person. 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 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 nerve), where they can cause inflammation and damage. In doing so, Zeposia may help protect against attacks on the nerves, reduce inflammation and damage to the nerves' protective coating and slow down the progression of disability.

Ask your doctor if you have any questions about how Zeposia works, or why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

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

Before you take Zeposia

When you must not take it

Do not take Zeposia if you have an allergy to:

- any medicine containing ozanimod
- any of the ingredients listed at the end of this leaflet.

Some of the general symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Zeposia if you:

- have had a heart attack, angina, stroke or warning of a stroke or certain types of heart failure in the last 6 months
- have certain types of irregular or abnormal heartbeats (arrhythmia)

- have untreated severe breathing problems when you sleep (severe sleep apnoea)

Do not take this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Follow your doctor's instructions carefully. If you have not fully understood these instructions, ask your doctor again before taking Zeposia.

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

Tell your doctor before taking Zeposia if you have or have had any of the following:

- a slow heart rate
- high blood pressure

- problems with your liver
- infection
- low levels of a type of white blood cell - called lymphocytes
- you 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.
- 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)
- 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.

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.

Tell your doctor if you are taking or have taken any of the following medicines:

- medicines that affect the immune system (e.g. ciclosporin)
- other medicines used to treat MS
 - beta interferon
 - glatiramer acetate
 - corticosteroids
 - natalizumab
 - mitoxantrone
 - teriflunomide
 - dimethyl fumarate
 - alemtuzumab
 - fingolimod
 - siponimod
 - cladribine
 - ocrelizumab

Taking Zeposia with these medicines may increase the risk of infection.

Tell your doctor if you or others notice worsening of your MS symptoms as well as any 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.

Tell your doctor if you have a headache, fever, neck pain, nausea and/or vomiting, sensitivity to light, confusion or others notices changes in your behaviour.

These symptoms may be due to a type of fungal (cryptococcal) infection in the brain.

Tell your doctor straight away if you develop 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.

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.

Tell your doctor if you are or may be pregnant or plan to become pregnant.

You should avoid becoming pregnant while taking Zeposia or in the three 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.

Tell your doctor if you are breast-feeding. You should not breastfeed while taking Zeposia.

This is because it is not known if this medicine passes into human milk.

If you have not told your doctor about any of the above, tell them before you start taking Zeposia.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines or have recently taken any other medicines, including any medicines that you buy without a

prescription from a pharmacy, supermarket or health food shop.

Some medicines and Zeposia may interfere with each other.

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, including other medicines used to treat MS, and drugs such as ciclosporin or eltrombopag
- gemfibrozil for fats or cholesterol in the blood
- 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Zeposia

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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.

Do not exceed the recommended dose

How to take it

Swallow the capsules whole with a full glass of water, once a day as directed by your doctor.

Zeposia can be taken with or without food.

When to take it

Take your medicine at about the same time each day.

How long to take it

Continue taking Zeposia until your doctor asks you to stop.

Your doctor will monitor your condition to check the medicine is working. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

During the first 14 days of treatment

If you have missed a dose of Zeposia on one day, 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.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you stop taking 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 you have worsening of your MS 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 take too much (overdose)

In Australia, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Zeposia.

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

Take the medicine pack and this leaflet with you.

While you are using Zeposia

Things you must do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Zeposia.
- If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Zeposia
- If you become pregnant while taking this medicine, tell your doctor immediately.
- 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.

Things you must not do

- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking Zeposia or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your doctor or pharmacist as soon as possible if your symptoms worsen while you are taking Zeposia.

Like all medicines, Zeposia can have side effects, although not everybody gets them and some are uncommon. Sometimes

they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following:

These are the more common side effects of your medicine

- 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
- sore throat (pharyngitis)
- respiratory (lung) infection

Tell your doctor immediately if you notice any of the following:

- 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)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist immediately if any of the side effects gets worse, or if you notice any other side effects not listed in this leaflet.

After taking Zeposia

Storage

Store the capsules in the original package.

Store in a cool dry place where the temperature stays below 25°C.

Do not store Zeposia or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, take any unused Zeposia capsules to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product description

What it looks like

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

- The 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.
- The 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.
- Maintenance pack containing 28 x 920 microgram capsules.

Ingredients

The active substance is ozanimod.

- 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).

The other ingredients in the capsules are:

Microcrystalline cellulose, silicon dioxide, croscarmellose sodium, magnesium stearate.

The capsule shells contain:

- 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.

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

Supplier

Zeposia is supplied in Australia by:

Celgene Pty Limited

Level 15, 60 City Road

Southbank VIC 3006.

Telephone: 1800 CELGENE (1800 235 4363)

® = Registered Trademark

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Australian Registration Numbers:

Zeposia 230 microgram and 460 microgram capsules initiation pack

AUST R 318801

Zeposia 920 microgram capsules blister pack

AUST R 318800