This brochure was approved according to the guidelines of the ministry of health on June 2024

ZEPOSIA® (ozanimod)

Patient/Caregiver Safety information Guide

Bristol Myers Squibb®

06/2024 2084-IL-2400029

What is ZEPOSIA and what is it used for

ZEPOSIA is a medicine for the following diseases:

- Multiple sclerosis
- Ulcerative colitis

ZEPOSIA contains the active substance ozanimod that belongs to a group of medicines which can reduce the number of certain white blood cells (lymphocytes) circulating freely round the body.

Multiple Sclerosis

ZEPOSIA is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease, as defined by clinical or imaging features .

Multiple sclerosis (MS) is a disease in which the immune system (the body's defences, including white blood cells) wrongly attacks the protective coating around the nerves in the brain and spinal cord. This stops the nerves from working properly and may result in symptoms such as numbness, difficulty in walking, and problems with vision and balance.

In relapsing remitting multiple sclerosis, attacks on the nerve cells are followed by periods of recovery. The symptoms may disappear during the recovery periods, but some problems may remain.

ZEPOSIA helps to protect against attacks on the nerves by stopping certain white blood cells reaching the brain and spine where they could cause inflammation and damage the protective coating of the nerves.

Ulcerative colitis

ZEPOSIA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

Ulcerative colitis is an inflammatory disease of the bowel, in which the immune system attacks the lining of the intestine, causing symptoms such as abdominal pain, diarrhea and bleeding.

ZEPOSIA can help to reduce the signs and symptoms of UC, by reducing the inflammation and stopping certain white blood cells from reaching the intestinal lining.

Do Not Take ZEPOSIA if:

- You are allergic to ozanimod or any of the other ingredients of this medicine;
- Your doctor has told you that you have a severely weakened immune system;
- You have had a heart attack, angina, stroke or mini-stroke (Transient Ischemic Attack - TIA), or certain types of severe heart failure in the last 6 months;

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- You have or have had in the past certain types of irregular or abnormal heartbeats (arrhythmia) – your doctor will check your heart before starting treatment;
- You have severe infection such as hepatitis or tuberculosis;
- You have cancer;
- You have severe liver problems;
- You are pregnant or a woman of childbearing potential not using effective birth control.

Taking ZEPOSIA for the First Time:

Before you start taking ZEPOSIA, read the package leaflet carefully as it has important information for you. Keep the leaflet as you may need to read it again while taking ZEPOSIA.

Your doctor will check your heart before you start treatment with ZEPOSIA

Your doctor will check your heart using an electrocardiogram (ECG) before you start taking ZEPOSIA. If you have a low heart rate or certain heart conditions, your doctor will monitor you for at least the first 6 hours after your first dose, including hourly checks of your pulse and blood pressure. Your doctor may obtain an ECG at the start and end of this 6 hour period.

Immediately report any symptoms of a low heart rate (such as dizziness, vertigo, nausea or palpitations) after taking ZEPOSIA for the first time. Since other medications may also lower your heart rate, it is important to tell all your doctors that you are taking ZEPOSIA.

Vaccinations

Your doctor will check if you are protected against chickenpox before you start taking ZEPOSIA. You may need to have the chickenpox vaccination 1 month before you begin taking ZEPOSIA.

Liver Function Test

Your doctor will check your liver function before you start taking ZEPOSIA.

Eye examination

If you have Diabetes, Inflammation of the eye (Uveitis), have now or have ever had retinal disease, your doctor may refer you for an eye examination either before you start or while you are taking ZEPOSIA.

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While Taking ZEPOSIA:

Treatment Interruptions

Tell your doctor if you stop taking ZEPOSIA, even if only for a short time. Depending on how long ago you stopped taking ZEPOSIA, your dose may need to be changed. Your doctor may need to decrease your dose of ZEPOSIA and then increase it gradually.

Neurologic Symptoms

Tell your doctor right away if you have any unexpected neurological and/or psychiatric symptoms/signs such as sudden severe headaches, confusion, seizures, progressive weakness, clumsiness, and vision changes, or accelerated neurological deterioration while you are taking ZEPOSIA.

Infection

While you are taking ZEPOSIA, you may get infections more easily. Tell your doctor right away if you have any signs and symptoms of an infection while you are taking ZEPOSIA, and for up to 3 months after you stop taking ZEPOSIA. ZEPOSIA may also reduce the number of white blood cells (lymphocytes) circulating round your body.

Your doctor may order a blood test to check your level of blood cells before you start taking ZEPOSIA and then check periodically theraftер.

Visual Symptoms

Tell your doctor right away if you have any symptoms of reduced vision while you are taking ZEPOSIA, and for up to 3 months after you stop taking ZEPOSIA.

Pregnancy

Do not use ZEPOSIA if you are pregnant or breast-feeding, or a woman of childbearing potential not using effective birth control. If used during pregnancy, ZEPOSIA can harm the unborn baby. Potential risks include loss of the unborn baby and birth defects.

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Before starting treatment with ZEPOSIA:

- Your doctor will explain the potential risks to an unborn baby if you become pregnant while taking ZEPOSIA;
- You must have a negative pregnancy test verified by your doctor and repeated at suitable intervals;
- You must use effective birth control while taking ZEPOSIA, including if your treatment is temporarily put on hold and for 3 months after you stop taking ZEPOSIA.

While taking ZEPOSIA treatment, you must not become pregnant. Your doctor will advise you of the harmful effects to the baby associated with ZEPOSIA treatment and ultrasound exams will be offered if needed. You should stop taking ZEPOSIA 3 months before planning a pregnancy. If you stop taking ZEPOSIA because you are pregnant or planning to have a baby, your disease symptoms may return.

Tell your doctor right away if you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby while taking ZEPOSIA and for 3 months after you stop taking ZEPOSIA.

Liver Function Test

Your doctor will ensure blood tests to check your liver function are performed on the 1st, 3rd, 6th, 9th, and 12th months of taking ZEPOSIA, and then periodically thereafter. If your test results indicate a problem with your liver, you may have to interrupt treatment with ZEPOSIA.

During treatment with ZEPOSIA, if you develop unexplained nausea, vomiting, pain on the right side of the stomach area (abdominal pain), tiredness, loss of appetite, yellowing of your skin or the whites of your eyes (jaundice) and/or dark urine, speak to your doctor straight away. These symptoms may be due to a problem with your liver.

Blood Pressure

Your doctor will check your blood pressure regularly while you are taking ZEPOSIA.

Skin Cancer

ZEPOSIA may increase your risk of skin cancer. You should limit your exposure to sun light and ultraviolet (UV) light, by wearing protective clothing and applying regular sunscreen (with high sun protection factor).

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Reporting Side Effects

If you experience any side effects, talk to your doctor or pharmacist. Additionally you can report side effects directly to the Israeli Ministry of Health by using the on-line form for reporting adverse events on the Home page of the Ministry of health website: www.health.gov.il or by entering the following link: https://sideeffects.health.gov.il

More information regarding how to report side effects can be found in the Patient Information Leaflet.

For more information please contact your doctor or pharmacist and refer to the patient information leaflet.

To obtain a copy of this document please contact Bristol Myers Squibb by phone: 03-5231021 or fax: 03-9226896

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Notes

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