ZEPOSIA®▼
(ozanimod)

Pregnancy-specific Patient Reminder Card
(For women of childbearing potential)

UK
Version 3.0

▼ This medicine is subject to additional monitoring. For more information, see the section on reporting side effects.

Bristol Myers Squibb™

Date of preparation: January 2022
2084-GB-2200006
Approved by MHRA: March 2022

Patient Information

If used during pregnancy, ozanimod can harm the unborn baby. Potential risks include loss of the unborn baby and birth defects.

- Do not use ozanimod if you are pregnant or breastfeeding or could become pregnant and are not using effective contraception.
- Before starting treatment with ozanimod:
  1. Your prescriber will explain the potential risks to an unborn baby if you become pregnant while taking ozanimod and will regularly inform you how to minimise the risks.
  2. You must use effective contraception while taking ozanimod and for 3 months after you stop taking ozanimod.
  3. Your doctor will carry out a pregnancy test and it must be negative. Pregnancy tests will also be checked during treatment.

- Tell your doctor immediately if you become pregnant during treatment with ozanimod or for 3 months after you stop taking it. Your doctor will discuss the risk of harmful effects to the baby associated with treatment and may arrange further tests such as an ultrasound. Ozanimod must be stopped during pregnancy;
- You should stop taking ozanimod 3 months before planning a pregnancy;
- If you stop taking ozanimod, tell your doctor right away if your disease related symptoms get worse as there is a possibility that the disease may return;
- Tell your doctor right away if you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby and for 3 months after you stop taking ozanimod.

Reporting of Side Effects

The safety of ozanimod is being closely monitored as it is a new medicine. It is important that any side effects are reported, even those not listed in the patient information leaflet that comes with the pack. You can help others by providing more information on the safety of your medication by reporting side effects.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Any side effects or pregnancies should also be reported to Bristol-Myers Squibb Medical Information on:
Tel: 0800 731 1736; **Email:** medical.information@bms.com

An electronic copy of this document can be viewed or downloaded from the electronic medicines compendium via:
www.medicines.org.uk/emc (Great Britain) and
www.emcmedicines.com/en-gb/northernireland (Northern Ireland).

If you have any questions or require further information, please contact Bristol-Myers Squibb Medical Information on:
Tel: 0800 731 1736; **Email:** medical.information@bms.com

Date of preparation: January 2022
2084-GB-2200006
Approved by MHRA: March 2022