

**ZEPOSIA<sup>®</sup>** ▼  
**(ozanimod)**

## Pregnancy Reminder Card

**(For women of childbearing potential)**

**UK**

**Version 2.0**

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

 **Bristol Myers Squibb™**

Date of preparation: December 2020  
RMP/ZEP/003/21-02/M (UK)  
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### **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 breast-feeding, or could become pregnant and are not using effective birth control.
- 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 birth control while taking ozanimod and for 3 months after you stop taking ozanimod.
  3. Your doctor will check a pregnancy test and it must be negative. Pregnancy tests will also be checked during treatment.

- You must inform your doctor immediately if you become pregnant during treatment with ozanimod. Your doctor will then 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 multiple sclerosis symptoms get worse as there is a possibility that the disease 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 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.

You can report side effects online via the Yellow Card website <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing [yellowcard@mhra.gov.uk](mailto:yellowcard@mhra.gov.uk);

- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

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](mailto: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](http://www.medicines.org.uk/emc). 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](mailto:medical.information@bms.com)