ZEPOSIA® (ozanimod)

Patient Card
(For women of childbearing potential)

UK
Version 4.0

This risk minimisation material fulfils the conditions of the marketing authorisation for ozanimod and has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

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2084-GB-2500003
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Bristol Myers Squibb®

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

Please report side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

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

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An electronic copy of this document can be viewed or downloaded from the electronic medicines compendium via 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