

ZEPOSIA® (ozanimod)

Patient Card

(For women of childbearing potential)

Ireland

Version 3.0

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can report side effects directly via HPRA Pharmacovigilance at www.hpra.ie. 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 1 800 749 749 or medical.information@bms.com.

This risk minimisation material fulfils the conditions of the marketing authorisation for ozanimod and has been approved by the Health Products Regulatory Authority (HPRA).

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 Bristol Myers Squibb®

Information on Pregnancy Prevention

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

- You must not use ozanimod if you are pregnant or could become pregnant and are not using effective contraception.

Before starting treatment with ozanimod:

1. Your doctor will explain the potential serious risks associated with ozanimod to an unborn baby and will regularly inform you how to minimise the risks.
2. Your doctor will carry out a pregnancy test and it must be negative.
3. You will need to use effective contraception to avoid becoming pregnant. Talk to your doctor about the most effective contraception options available to you.

While you are taking ozanimod and after you stop treatment:

1. You must use effective contraception without interruption while taking ozanimod and for 3 months after you stop taking it. Pregnancy tests will be repeated during treatment.
2. Tell your doctor immediately if you become pregnant or think you may be pregnant whilst taking 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 ultrasound examinations will be offered if needed. Ozanimod must be stopped during pregnancy.
3. If you are planning to get pregnant, talk to your doctor. Your doctor will need to stop your treatment 3 months before planning a pregnancy.
4. If your treatment is stopped, there is a possibility that the disease may return. Tell your doctor right away if your disease related symptoms get worse after stopping treatment.