PREGNANCY-SPECIFIC PATIENT CARD

Velsipity (etrasimod) ▼
Pregnancy-Specific Patient Card

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. For further information, see section on reporting side effects.

Version: 1.0

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Patient information

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

- Do not use etrasimod if you are pregnant or breastfeeding or could become pregnant and are not using effective contraception.
- Before starting treatment with etrasimod:
  1. Your prescriber will explain the potential risks to an unborn baby if you become pregnant while taking etrasimod and will regularly inform you how to minimise the risks.
  2. You must use effective contraception while taking etrasimod and at least 14 days after you stop taking etrasimod.
  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 etrasimod or for at least 14 days 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. Etrasimod must be stopped during pregnancy.
- Tell your doctor right away if you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby.
- Keep this card with you and show it to any doctor or pharmacist involved in your care.
- See the VELSIPITY package leaflet for more information.

Reporting side effects

The safety of etrasimod is being closely monitored as it is a new medicine. It is important that any side effects should be 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.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000
E: postlicensing.medicinesauthority@gov.mt

Alternatively, you may also report such events promptly to Pfizer at Pfizer Hellas S.A., 243 Messoghion Ave. N.Psychiko, Athens GR-15451, Greece. Pfizer Hellas Pharmacovigilance Department contact details: +30 210 67 85 908 and +30 210 67 85 808 (24hour line), fax: +30 210 81 99 096, or via the webportal Pfizer's Adverse Event Reporting Portal (pfizersafetyreporting.com). Healthcare professionals should report adverse events or reactions by brand name and batch number.

Other Information (please complete)

Patient's Name: _____

Doctor's Name: _____

Doctor's Phone: _____

Doctor's Fax:_____

If you stop taking VELSIPITY, keep this card with you for at least 2 months after taking the last dose of VELSIPITY.