

Velsipity[®]▼ (etrasimod)

Pregnancy-Specific Patient Card (for women of childbearing potential)

This educational material is part of the marketing authorisation and has been approved by the HPRA.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Please see back page for details on reporting side effects.



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Patient information on pregnancy prevention

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 could become pregnant and are not using effective contraception.
- Keep this card with you and show it to any doctor or pharmacist involved in your care.
- See the etrasimod package leaflet for more information.

- Before starting treatment with etrasimod:
 1. Your doctor 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. Your doctor will carry out a pregnancy test and it must be negative
 3. Ask your doctor about reliable methods of contraception

- While you are taking etrasimod and after stopping treatment:
 1. You must use effective contraception while taking etrasimod and for at least 14 days after you stop taking it.
 2. Pregnancy tests will be repeated regularly during treatment

3. Tell your doctor immediately if you become pregnant or think you may be pregnant during treatment with etrasimod or within 14 days of stopping your treatment. Your doctor will discuss the risk of harmful effects to the baby associated with treatment and will arrange further tests such as an ultrasound to monitor the health of the unborn baby. Etrasimod must be stopped immediately if you become pregnant
4. Tell your doctor if you are planning to have a baby. Etrasimod treatment must be stopped at least 14 days before trying to conceive

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 medicine by reporting side effects.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via HPRA pharmacovigilance at www.hpra.ie. Any side effects or pregnancies may also be reported to Pfizer Medical Information by telephone on 1800 633 363.