

Velsipity▼® (etrasimod)

PATIENT/CAREGIVER GUIDE

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

This guide is intended for people who have been prescribed etrasimod and their caregivers. It includes details of important safety information that you should be aware of before starting treatment. Before you start taking etrasimod, read the patient information leaflet carefully as it has important information for you. Keep the leaflet as you may need to read it again while taking etrasimod

▼ 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. 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.

An electronic copy of this guide is available at www.hpra.ie (enter 'Velsipity' in the 'Find a medicine' search box and click 'EdM' under the 'Documents' column).



Do not take etrasimod if:

- You have had a heart attack, unstable angina pectoris (chest pain caused by interruptions in the heart's blood supply that occurs at rest or without an obvious trigger), stroke, transient ischaemic attack (TIA, also known as a mini-stroke) or certain types of severe heart failure in the last 6 months.
- You have certain types of arrhythmia (irregular or abnormal heartbeat) – your doctor will check your heart before starting treatment.
- You are pregnant or a woman of childbearing potential not using effective contraception. For further information, see 'Pregnancy information for women of childbearing potential' in this guide.

BEFORE STARTING ETRASIMOD TREATMENT

- Your doctor will check your heart using an electrocardiogram (ECG; a test of the heart's electrical activity).
- Your doctor will request blood tests to monitor your liver function.

WHILE YOU ARE TAKING ETRASIMOD

Slow heart rate and irregular heart rhythm

- Etrasimod can cause a temporary decrease in heart rate and other heart rhythm disorders when starting treatment. If this happens, you may feel dizzy, nauseous, tired, have vertigo, be consciously aware of your heartbeat, or your blood pressure may drop.
- If these effects are severe, tell your doctor immediately, because you may need treatment right away.

First dose monitoring for patients with certain heart conditions

- If you have certain heart conditions, your doctor will also monitor you for at least the first 4 hours after your first dose.
- Your doctor will ask you to stay at the hospital or clinic for 4 hours and will measure your pulse and blood pressure every hour after taking the first dose of etrasimod.
- You should have an ECG performed before the first dose of etrasimod and after the 4-hour monitoring period.
- If after the 4-hour period you have a very slow or decreasing heart rate, or if your ECG shows abnormalities, you may need to be monitored for a longer period until these have resolved.

Restarting treatment after stopping for 7 or more days in a row

- Tell your doctor if you have stopped etrasimod for 7 or more days in a row, because your doctor may need to re-check your heart using an ECG before starting the treatment again.

Etrasimod and other medicines

- Etrasimod can interact with medicines that slow your heart rate, so it is important to tell any healthcare professional treating you (such as a doctor, dentist, pharmacist, or nurse) that you are being treated with etrasimod.

Infections

Etrasimod lowers the levels of white blood cells in your blood (particularly the lymphocyte count). White blood cells fight infection. While you are taking etrasimod (and for up to about 2 weeks after you stop taking it), you may be more likely to get infections, and any infection that you already have may get worse.

Talk to your doctor if you develop an infection. If you think you have an infection, have a fever, feel like you have the flu, have shingles, or have a headache accompanied by a stiff neck, with sensitivity to light, nausea, rash, and/or confusion or seizures (fits) (these may be symptoms of meningitis and/or encephalitis caused by a fungal or herpes viral infection), contact your doctor straight away, because it could be serious and life-threatening.

Cases of progressive multifocal leukoencephalopathy (PML) have been reported with medicines similar to etrasimod. PML is a rare viral brain infection that may lead to severe disability or death. PML symptoms include disturbance of vision, progressive

weakness, clumsiness, memory loss, or confusion. If you develop any of these symptoms, speak to your doctor straight away. Your doctor will consider performing further tests to evaluate this condition and will stop your treatment with etrasimod if PML is confirmed.

Vision problems

Etrasimod can cause a problem with your vision called macular oedema (swelling of the macula, the central part of the retina at the back of the eye). The risk of developing macular oedema is higher if you have diabetes, uveitis (inflammation of the uvea, the layer beneath the white of the eyeball), or certain other eye problems. If you have any of these conditions, your doctor will check your vision before you start taking etrasimod and regularly during treatment. If you do not have these conditions, your doctor will check your vision within 3-4 months after starting treatment. Tell your doctor about any changes in your vision while on etrasimod.

Call your doctor straight away if you have any of the following:

- blurriness or shadows in the centre of your vision;
- a blind spot in the centre of your vision;
- sensitivity to light;
- unusually coloured (tinted) vision.

Cancer

Etrasimod weakens your immune system. This increases your risk of developing cancers, in particular skin cancers. Skin cancers have been reported with medicines similar to etrasimod. Talk to your doctor straight away if you notice any skin nodules (e.g. shiny pearly nodules), patches, or open sores that do not heal within weeks. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (e.g. unusual moles) with a change in colour, shape, or size over time. Since there is a risk for skin cancer, you should limit your exposure to sunlight and UV (ultraviolet) light by wearing protective clothing and regularly applying sunscreen (with high sun protection factor).

Nervous system disorders

Posterior reversible encephalopathy syndrome (PRES) is a condition where the brain swells. PRES symptoms include headache, changes in vision, reduced awareness, confusion, and seizures (fits). If you develop any of these symptoms, speak to your doctor straight away.

Liver function tests

Etrasimod may affect your liver function. Tell your doctor straight away if you develop any of the following symptoms: yellowing of your skin or the whites of your eyes, abnormally dark urine (brown coloured), pain on the right side of your stomach area (abdomen), tiredness, feeling less hungry than usual or unexplained nausea and vomiting.

Before, during and after the treatment, your doctor will request blood tests to monitor your liver function.

Pregnancy information for women of childbearing potential

Do not use etrasimod during pregnancy, if you are trying to become pregnant, or if you are a woman who could become pregnant and you are not using effective contraception. If used during pregnancy, etrasimod can harm the unborn baby.

Before you start treatment with etrasimod, your doctor will explain the risk to you and ask you to do a pregnancy test in order to ensure that you are not pregnant.

Your doctor will give you a patient card which explains why you should not become pregnant while taking etrasimod. It also explains what you should do to avoid becoming pregnant while you are taking etrasimod.

You must use effective contraception during treatment and for at least 14 days after stopping treatment.

Pregnancy tests will be repeated regularly during treatment.

If you do become pregnant while taking etrasimod, tell your doctor straight away. Etrasimod must be stopped immediately if you become pregnant.

REPORTING OF SIDE EFFECTS

The safety of etrasimod 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.

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 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. Please report as much information as possible to support the continued understanding on the safety of this medicine.