PATIENT/CAREGIVER GUIDE

Velsipity (etrasimod) ▼

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Version: 1.0 Date of approval: 06/2024

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

By reporting side effects, you can help provide more information on the safety of this medicine.

Any side effects or pregnancies may also be reported 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.

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Before starting Velsipity
Before you start taking Velsipity, 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 Velsipity.
Velsipity may cause birth defects and miscarriage to an unborn baby. If you are a woman of childbearing potential, you should also receive the Pregnancy Specific Patient Card. Please read this card carefully as it contains important information.

Do not take Velsipity if:
- if your healthcare professional has told you that you have a severely weakened immune system;
- 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;
- if you have certain types of arrhythmia (irregular or abnormal heartbeat) – your doctor will check your heart before starting treatment;
- if you have a severe active infection or active chronic infection, such as hepatitis (inflammation of the liver) or tuberculosis;
- if you have cancer;
- if you have severe liver problems;
- if you are pregnant or a woman of childbearing potential not using effective contraception.

WHILE YOU ARE TAKING VELSIPITY

<u>Slow heart rate and irregular heart rhythm</u>
Before you start taking Velsipity, your doctor will check your heart using an electrocardiogram (ECG; a test of the heart's electrical activity). This is because Velsipity can cause a temporary decrease in heart rate and other heart rhythm disorders when starting treatment. When this happens, you may feel dizzy, nauseous, vertigo or tired or be consciously aware of your heartbeat, or your blood pressure may drop. If these effects are severe, tell your doctor, because you may need treatment right away.

If you restart treatment again after stopping for 7 or more days in a row, your doctor may re-check your heart using an ECG.

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 Velsipity.
You should have an ECG performed before the first dose of Velsipity 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. Caution should be taken with concomitant use of medicines that slow the heart rate. Patients should tell any doctor they see that they are being treated with Velsipity.

<u>Infections</u>
Velsipity lowers the levels of white blood cell in your blood (particularly the lymphocyte count). White blood cells fight infection. While you are taking Velsipity (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 Velsipity. 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 Velsipity if PML is confirmed.

Macular oedema
Velsipity 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). Your doctor will check your vision around the time you start taking Velsipity and at any time you notice vision changes during your treatment. Tell your doctor about any changes in your vision. 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 around the time you start taking Velsipity and regularly during treatment.

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
Velsipity weakens your immune system. This increases your risk of developing cancers, in particular skin cancers. Skin cancers have been reported with medicines similar to Velsipity. 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).

Posterior reversible encephalopathy syndrome (PRES)
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.

Vaccinations
If you need to receive a vaccine, seek your doctor’s advice first. Vaccines may not work as well as they should during your treatment with Velsipity. You are advised to make sure your vaccinations are

up-to-date before you start treatment. So-called live vaccines may trigger the infection that they are supposed to prevent and should therefore be given at least 4 weeks before you start treatment, or at least 2 weeks after you stop taking Velsipity.

Liver function tests
Velsipity 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.

Women of childbearing potential
If used during pregnancy, Velsipity can harm the unborn baby. Before you start treatment with Velsipity, 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 Velsipity. It also explains what you should do to avoid becoming pregnant while you are taking Velsipity. You must use effective contraception during treatment and for at least 14 days after stopping treatment.

REPORTING OF SIDE EFFECTS
The safety of Velsipity 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.
Please report suspected adverse drug reactions promptly to the Maltese Medicines Authority, using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sending 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. Please report as much information as possible to support the continued understanding on the safety of this medicine.

- All the educational materials including Patient/Caregiver Guide, the Prescriber Checklist and the Pregnancy-Specific Patient Card are available at: https://medicinesauthority.gov.mt/rmm.

- In case you need more copies of the Patient/Caregiver Guide and/or the Pregnancy-Specific Patient Card, please call Pfizer's Local Representative, Vivian Corporation Ltd.: 00356 22588600.