TRADENAME (VELSIPITY) ▼ PRESCRIBER CHECKLIST

Patient:

Date:_____

▼ 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.

Please report suspected adverse drug reactions (ADRs) to the Maltese Medicines Authority. 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.

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This treatment checklist intends to remind you of the risks associated with the use of VELSIPITY and the recommended clinical actions to support appropriate use. Please use the checklist to confirm appropriate clinical action. For further information, please refer to the Summary of Product Characteristics (SmPC) for further details.

Prior to treatment with Velsipity

Lists of tests and checks to be conducted prior to treatment initiation with Velsipity

Provide all patients/caregivers with a patient/caregiver guide	☐
Provide all women of child bearing potential with a pregnancy-specific card	☐

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Check baseline electrocardiogram (ECG) to determine whether any pre-existing cardiac abnormalities are present.	☐
Velsipity should not be used in patients: • who in the last 6 months experienced myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attack (TIA), decompensated heart failure requiring hospitalisation, or New York Heart Association (NYHA) Class III/IV heart failure. - with history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.	☐
Consult a cardiologist before initiating treatment to determine if Velsipity can safely be initiated and to determine the most appropriate monitoring strategy, when initiating Velsipity in patients with: a history of symptomatic bradycardia and other pre-existing cardiac conditions.	☐
Caution should be taken when initiating Velsipity in patients taking medicines known to decrease heart rate.	☐
Velsipity should not be used in patients with any active infection or live attenuated vaccine immunisations within the last 4 weeks.	☐
Check patient's recent liver function test results for transaminase and bilirubin levels • Velsipity must not be used in patients with severe hepatic impairment.	☐
A recent complete blood count (CBC), including lymphocyte count, should be obtained. • Velsipity should not be used in patients with an absolute lymphocyte count $< 0.2 \times 10^9$/L.	☐

Confirm a negative pregnancy test result in women of childbearing potential prior to starting treatment. **Note the following:** • In women of childbearing potential, a pregnancy test must be negative and patients must be counselled on risk for the foetus. • Provide a pregnancy-specific patient card to all female patients of childbearing potential. • Velsipity must not be used during pregnancy or in women of childbearing potential not using effective contraception.	☐
An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients. • Patients with a macula oedema should not use Velsipity.	☐

Monitoring activities during and after treatment

In patients with resting heart rate < 50 bpm, second-degree AV block [Mobitz type I], or a history of myocardial infarction or heart failure, monitoring is recommended after the first dose: • 4-hour monitoring for signs and symptoms of symptomatic bradycardia (including dizziness), and hourly pulse and blood pressure. An ECG prior to and at the end of this 4-hour period is recommended.	
Additional monitoring is recommended in patients, if at the end of 4-hour period: • Heart rate is < 45 bpm. • Heart rate is the lowest value post dose, suggesting that the maximum decrease in heart rate may not have occurred yet. • ECG shows evidence of a new onset second-degree or higher AV block. • QTc interval is ≥ 500 msec.	
Recommendation for measuring blood pressure regularly while on treatment.	☐

When reinitiating treatment after an interruption of 7 or more consecutive days, consideration may be given to repeating the baseline ECG and/or monitoring depending on the results of the first evaluation, change in patient characteristics, and duration of interruption.	☐
Periodic assessments of CBC during treatment.	☐
Treatment interruption if a patient develops a serious infection.	☐

Physicians should be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of PML. If PML is suspected, treatment with etrasimod should be suspended until PML has been excluded by an appropriate diagnostic evaluation.	☐

Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects during such therapy.	Yes ☐ No☐
The use of live attenuated vaccine should be avoided for at least 2 weeks after discontinuation of treatment with Velsipity.	☐
Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter. • Velsipity should be discontinued if significant liver injury is confirmed.	☐

Women of childbearing potential should use effective contraception to avoid pregnancy during treatment and for at least 14 days after stopping Velsipity. • Pregnancy testing should be repeated regularly. If a woman becomes pregnant during treatment, Velsipity must be immediately discontinued.	☐
Patients with a history of diabetes mellitus, uveitis, or an underlying/co-existing retinal disease should undergo an ophthalmic evaluation regularly. An ophthalmic evaluation should be made in patients developing a change in vision.	☐
Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies. Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy.	☐
Patients should be counselled for symptoms of PRES. • A complete physical and neurological examination should be done and an MRI considered for patients who develop unexpected neurological or psychiatric symptoms/signs or any symptoms suggestive of an increase of intracranial pressure, or accelerated neurological deterioration. • Treatment with Velsipity should be discontinued if PRES is suspected.	☐