

Velsipity

(Etrasimod)

Prescriber Checklist

Patient: _____

Date: _____

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 Prescribing Information 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.	<input type="checkbox"/>
Provide all women of child bearing potential with a pregnancy-specific card.	<input type="checkbox"/>
Check baseline electrocardiogram (ECG) to determine whether any pre-existing cardiac abnormalities are present.	<input type="checkbox"/>
Velsipity should not be used in patients: <ul style="list-style-type: none">• 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.	<input type="checkbox"/>
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: <ul style="list-style-type: none">• History of symptomatic bradycardia and other pre-existing cardiac conditions.	<input type="checkbox"/>

Caution should be taken when initiating Velsipity in patients taking medicines known to decrease heart rate.	<input type="checkbox"/>
Velsipity should not be used in patients with any active infection or live attenuated vaccine immunisations within the last 4 weeks.	<input type="checkbox"/>
Check patient's recent liver function test results for transaminase and bilirubin levels <ul style="list-style-type: none"> Velsipity must not be used in patients with severe hepatic impairment. 	<input type="checkbox"/>
A recent complete blood count (CBC), including lymphocyte count, should be obtained. <ul style="list-style-type: none"> Velsipity should not be initiated in patients with an absolute lymphocyte count $< 0.2 \times 10^9/L$. 	<input type="checkbox"/>
Confirm a negative pregnancy test result in women of childbearing potential prior to starting treatment. Note the following: <ul style="list-style-type: none"> 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. 	<input type="checkbox"/>
An ophthalmic evaluation of the fundus, including the macula, is recommended in patients with history of diabetes mellitus, uveitis, and/or retinal disease, who are at increased risk of developing macular oedema. <ul style="list-style-type: none"> Patients with macular oedema should not use Velsipity. 	<input type="checkbox"/>

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: <ul style="list-style-type: none"> 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. 	<input type="checkbox"/>
Additional monitoring is recommended in patients, if at the end of 4-hour period: <ul style="list-style-type: none"> 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. 	<input type="checkbox"/>
Recommend measuring blood pressure regularly while on treatment.	<input type="checkbox"/>
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.	<input type="checkbox"/>
Periodic assessments of CBC during treatment.	<input type="checkbox"/>
Treatment interruption if a patient develops a serious infection.	<input type="checkbox"/>
Physicians should be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of PML. If PML is suspected, treatment with Velsipity should be suspended until PML has been excluded by an appropriate diagnostic evaluation.	<input type="checkbox"/>
Please confirm if any 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No
The use of live attenuated vaccine should be avoided for at least 2 weeks after discontinuation of treatment with Velsipity.	<input type="checkbox"/>

<p>Hepatic enzymes should be monitored at months 1, 3, 6, 9, and 12 on therapy and periodically thereafter.</p> <ul style="list-style-type: none"> • Velsipity should be discontinued if significant liver injury is confirmed. 	<input type="checkbox"/>
<p>Women of childbearing potential should use effective contraception to avoid pregnancy during treatment and for at least 14 days after stopping Velsipity.</p> <ul style="list-style-type: none"> • Pregnancy testing should be repeated regularly. If a woman becomes pregnant during treatment, Velsipity must be immediately discontinued. 	<input type="checkbox"/>
<p>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.</p> <p>In patients without risk factors for macular oedema (such as history of diabetes, uveitis, and/or retinal disease), an ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months after starting Velsipity treatment (cases reported with Velsipity occurred within this timeframe) and at any time if there is a change in vision while taking Velsipity.</p>	<input type="checkbox"/>
<p>Patients should be cautioned against exposure to sunlight without protection to prevent development of cutaneous malignancies.</p> <ul style="list-style-type: none"> • Patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy. 	<input type="checkbox"/>
<p>Patients should be counselled for symptoms of PRES.</p> <ul style="list-style-type: none"> • 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. 	<input type="checkbox"/>

Adverse events can be reported directly to the Ministry of Health using the adverse events reporting portal which is available on the home page of the Ministry of Health website: www.health.gov.il

or by this link:
<https://sideeffects.health.gov.il>

Side effects can also be reported to Pfizer by email:
isr.aereporting@pfizer.com

This Prescriber Checklist, format and content have been approved by the Ministry of Health in February 2025.

