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Velsipity® (etrasimod)

Healthcare Professional Guide

VELSIPITY® is a once-daily, oral sphingosine-1-phosphate (S1P) receptor modulator indicated for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had inadequate response, loss of response, or intolerance to conventional, biologic or Janus kinase (JAK) inhibitor therapies.[1]

Prescribers should provide all patients and caregivers with the VELSIPITY Patient and Caregiver Guide. All female patients of childbearing potential should be provided with a Pregnancy-Specific Patient Card (located inside the VELSIPITY Patient and Caregiver Guide).

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Assessments to determine if VELSIPITY is appropriate for your patient

		WHAT TO DO AND WHY
Pre-first dose testing for ALL patients		
 **Blood tests**[1]	☐	Obtain a recent complete blood count (i.e. within the last 6 months or after discontinuation of prior UC therapy) – including lymphocyte count, transaminase levels and bilirubin level.
		• The initiation of VELSIPITY in patients with any active infection should be delayed until the infection is resolved • VELSIPITY should not be used in patients with an absolute lymphocyte count <0.2 × 10^9/L • VELSIPITY causes a reduction in peripheral blood lymphocyte count, with 90% of patients returning to the normal range within 1 to 2 weeks of discontinuation based on a population pharmacokinetic/pharmacodynamic model • VELSIPITY is not recommended in severe hepatic impairment
 **Cardiac evaluation**[1]	☐	Obtain an electrocardiogram (ECG/EKG) to assess for pre-existing cardiac conduction abnormalities.
		• In patients with history of symptomatic bradycardia, recurrent cardiogenic syncope or severe untreated sleep apnoea and other pre-existing cardiac conditions, cardiologist advice should be obtained before initiation • Initiation of VELSIPITY may result in a transient decrease in heart rate and atrioventricular (AV) conduction delays
 **Immunisations**[1]	☐	If live attenuated vaccine immunisations are required, administer at least 4 weeks prior to initiation of VELSIPITY.
		• The use of live attenuated vaccine may carry the risk of infection • Update immunisations in line with current immunisation guidelines prior to initiating VELSIPITY therapy
Pre-first dose activities for SELECT patients		
 **Pregnancy counselling**[1]	☐	Before initiation with VELSIPITY, women of childbearing potential must be counselled on the potential for a serious risk to the fetus. Pregnancy must be excluded before treatment initiation.
		• These patients should be provided with a Pregnancy-Specific Patient Card (found in the VELSIPITY Patient and Caregiver Guide)
 **Eye exam**[1]	☐	In patients with a history of diabetes mellitus, uveitis, or retinal disease, obtain an evaluation of the fundus, including the macula prior to initiation of VELSIPITY. These patients should have follow up evaluations while receiving therapy.
		• S1P modulators, including VELSIPITY, have been associated with an increased risk of macular oedema • In patients who develop macular oedema, it is recommended that VELSIPITY be discontinued

VELSIPITY should not be used in patients:[1]

- Who in the last 6 months experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalisation, or New York Heart Association (NYHA) Class III/IV heart failure
- With a history or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
- With hypersensitivity to the active substance or to any of the excipients
- During pregnancy and in women of childbearing potential not using effective contraception
- Who are breast-feeding
- With active malignancies

Monitoring recommendations for ALL patients during and after treatment with VELSIPITY

 **Blood tests**[1]	☐	Clinicians should monitor complete blood count periodically during treatment.
		• Treatment with VELSIPITY should be interrupted in patients with a confirmed absolute lymphocyte count <0.2 × 10^9/L until the level reaches >0.5 × 10^9/L when re-initiation of VELSIPITY can be considered
 **Infections**[1]	☐	Monitor for signs and symptoms of an infection.
		• If a patient develops a serious infection, consider interrupting treatment with VELSIPITY • Because residual pharmacodynamic effects, such as lowering effects on peripheral lymphocyte count, may persist up to 2 weeks after discontinuation of VELSIPITY, vigilance for infection should be continued throughout this period • Caution should be used when co-administering VELSIPITY and antineoplastic, immune-modulating or immunosuppressive (including corticosteroid) therapies to patients, because of the risk of additive immune system effects during such therapy
 **Blood pressure**[1]	☐	Blood pressure should be monitored during treatment with VELSIPITY and managed appropriately.
 **Immunisations**[1]	☐	Avoid the use of live attenuated vaccine during VELSIPITY treatment and for at least 2 weeks after discontinuation of treatment with VELSIPITY.
 **Eye exam**[1]	☐	An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients at any time if there is any change in vision while taking VELSIPITY.
		• If macular oedema is confirmed, treatment with VELSIPITY should be discontinued
 **Liver function**[1]	☐	Monitor hepatic enzymes in patients who develop symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine.
		• VELSIPITY should be discontinued if significant liver injury is confirmed
 **Skin exam**[1]	☐	Perform periodic skin examinations and check for skin lesions.
		• If a suspicious skin lesion is observed, it should be promptly evaluated, as cases of malignancies (including skin malignancies) have been reported in patients treated with S1P receptor modulators
	☐	Patients treated with VELSIPITY should be cautioned against exposure to sunlight without protection.
		• These patients should not receive concomitant phototherapy with UV-B-radiation or PUVA-photochemotherapy
 **Neurological**[1] (PRES and PML)	☐	Patients should be counselled for symptoms of posterior reversible encephalopathy syndrome (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. Be vigilant for clinical symptoms or unexplained neurologic findings that may be suggestive of progressive multifocal leukoencephalopathy (PML).

		• PRES:
		  ◦ Rare cases of PRES have been reported in patients receiving other S1P receptor modulators
		  ◦ Treatment with VELSIPITY should be discontinued if PRES is suspected
		• PML:
		  ◦ If PML is suspected, treatment with VELSIPITY should be suspended until PML has been excluded by an appropriate diagnostic evaluation

Monitoring recommendations for SELECT patients during and after treatment with VELSIPITY

 **Cardiac monitoring**[1]	☐	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) • Hourly pulse and blood-pressure measurement • 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

 **Pregnancy**[1]	☐	Women of childbearing potential should use effective contraception to avoid pregnancy during treatment and for 10 days after stopping VELSIPITY. If a woman becomes pregnant during treatment, VELSIPITY must be immediately discontinued.

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PBS Information: Authority required. Please refer to the PBS schedule for full authority information.

Before prescribing, please review full Product Information available here.

Reference: 1. VELSIPITY Product Information.

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