

UC SYMPTOMS CAN CAUSE
CHAOS
FOR YOUR PATIENTS^{1,2}

HELP
CALM
THEIR CHAOS³



Not an actual patient.

Not an actual patient.

Getting your patients started on³

 **Velsipity**TM
(etrasimod) 2mg tablets

A once-daily oral S1P receptor modulator indicated for patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, a lost response, or were intolerant to either conventional therapy or a biologic agent³








VELSIPITY requires one-time, straightforward, pre-first-dose testing.³



Complete the pre-first-dose testing checklist

Important steps for starting patients on VELSIPITY™ (etrasimod)

[FOR GERMANY AND THE UK, ADD COPY THAT MENTIONS RESPECTIVE GUIDELINES REGARDING PRE-FIRST-DOSE TESTING, eg: THE BRITISH SOCIETY OF GASTROENTEROLOGY SUPPORTS PRE-FIRST-DOSE TESTING TESTING FOR ALL SIP MODULATORS]

CONFIRM		WHAT TO DO AND WHY
For all patients		
 Blood work³	<input checked="" type="checkbox"/>	Obtain a recent (ie, within the last 6 months or after discontinuation of prior UC therapy) complete blood count, including lymphocyte count and recent (ie, within last 6 months) transaminase and bilirubin levels ³
		<ul style="list-style-type: none"> To start treatment, blood levels need to be assessed³ VELSIPITY causes a reduction in peripheral blood lymphocyte count, with 90% of patients returning to the normal range within 1 to 2 weeks of stopping therapy³ Elevations of aminotransferases may occur in patients receiving VELSIPITY³ The initiation of VELSIPITY in patients with any active infection should be delayed until the infection is resolved³
 Electrocardiogram (ECG or EKG)³	<input checked="" type="checkbox"/>	Obtain a one-time ECG to determine whether preexisting conduction abnormalities* are present ³
		<ul style="list-style-type: none"> This will help screen for any preexisting cardiac abnormalities^{3*}: <ul style="list-style-type: none"> Initiation of VELSIPITY may result in a transient decrease in heart rate and atrioventricular (AV) conduction delays In patients with preexisting conditions, advice from a cardiologist should be sought¹ 99% of patients who screened for ELEVATE UC 52 and ELEVATE UC 12 were eligible for treatment following the cardiac assessment⁴
For select patients		
 Pregnancy test¹	<input checked="" type="checkbox"/>	Administer a pregnancy test to all women of childbearing potential; before initiation of treatment, they must be counseled on the potential for a serious risk to the fetus, they must have a negative pregnancy test, and they must use effective contraception during treatment. Prescribers should provide all patients and caregivers with the patient and caregiver guide and provide a pregnancy-specific patient card to all female patients of childbearing potential ³
		<ul style="list-style-type: none"> Due to the risk to the fetus, VELSIPITY is contraindicated during pregnancy and in women of childbearing potential not using effective contraception³
 Ophthalmic assessment¹	<input checked="" type="checkbox"/>	Obtain an ophthalmic evaluation in patients with a history of diabetes mellitus, uveitis, or underlying or coexisting retinal disease prior to treatment initiation. These patients should also have follow-up evaluations while receiving therapy ³
		<ul style="list-style-type: none"> This will help screen for any preexisting eye conditions³ S1P receptor modulators, including VELSIPITY, have been associated with an increased risk of macular oedema³
 For patients with certain cardiac abnormalities	<input checked="" type="checkbox"/>	Monitor certain patients (those with resting heart rate <50 bpm, second-degree [Mobitz type I] AV block, or a history of myocardial infarction or heart failure) for signs and symptoms of symptomatic bradycardia for 4 hours after their first dose ³
		<ul style="list-style-type: none"> The initiation of treatment with S1P receptor modulators, including VELSIPITY, can lead to transient decreases in heart rate and AV conduction delays³ Patients who experienced bradycardia were generally asymptomatic: Few patients experienced symptoms, such as dizziness, and these symptoms resolved without intervention

Prior to initiating VELSIPITY, it is also important to³:

- **Review vaccination records** and update immunizations in accordance with the latest guidance
- **Review history for medications** that may affect heart rhythm or may have immunosuppressive effects

Monitor for certain safety signals—no additional required scheduled monitoring^{3†}

*Eg, second-degree (Mobitz type I) AV block, myocardial infarction, and heart failure.³

[†]Cardiologist advice should be obtained before initiation of VELSIPITY in the following patients to determine overall benefit risk and the most appropriate monitoring: in patients with significant QT prolongation (QTcF ≥450 msec in males, ≥470 msec in females); in patients with arrhythmias requiring treatment with class Ia or class III anti-arrhythmic drugs; in patients with ischemic heart disease, history of cardiac arrest, cerebrovascular disease, or uncontrolled hypertension; and in patients with history of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnea.³

[‡]Eg, infections, eye exam, blood pressure, and skin exam.³

Discuss these tests with your patients



Your patients will most likely have questions about the pre-first-dose testing requirements before starting VELSIPITY. The information provided in these materials can help them better understand which tests need to be performed and why those tests are important.



“WHY ARE YOU CHECKING MY HEART FOR A UC MEDICATION?”

- All patients who may be prescribed VELSIPITY will have an initial ECG³:
 - An ECG is a simple, noninvasive test that records the heart rate, heart rhythm, and electrical impulses to uncover certain cardiac problems⁵
- An ECG can confirm the absence or presence of a preexisting heart condition or conditions³
- For patients who did not have certain heart conditions, 99% were able to start on treatment following the ECG in VELSIPITY ELEVATE UC 52 and ELEVATE UC 12 clinical trials⁴
- Some patients taking VELSIPITY in the clinical trials experienced a temporary slowing of their heart rate after taking the first dose³:
 - In the clinical trials, 1% to 3% of patients taking VELSIPITY experienced a slowing of their heart rate after taking the first dose⁶
 - For those patients who experienced a temporary slowing of their heart rate, few experienced symptoms, such as dizziness, and these symptoms resolved without intervention⁶



“WHY DO I NEED TO HAVE MY EYES CHECKED?”

- A baseline eye exam is intended to help monitor any changes in patients' eye health throughout treatment³
- S1P receptor modulators, including VELSIPITY, have been associated with an increased risk of macular oedema³:
 - While on treatment with VELSIPITY, patients should let their HCPs know if they experience any vision changes

Please share any other appropriate VELSIPITY materials with your patients after prescribing VELSIPITY.



We are dedicated to helping make pre-first-dose testing as straightforward as possible for your patients.

For additional information, please reach out to your sales representative.

[PLACEHOLDER FOR LOCAL MARKET SUPPORT PROGRAM LANGUAGE WHERE APPLICABLE]

References: **1.** Peyrin-Biroulet L, Van Assche G, Sturm A, et al. Treatment satisfaction, preferences and perception gaps between patients and physicians in the ulcerative colitis CARES study: a real world-based study. *Dig Liver Dis.* 2016;48(6):601-607. **2.** Dubinsky MC, Watanabe K, Molander P, et al; The Global UC Narrative Survey Panel. Ulcerative Colitis Narrative global survey findings: the impact of living with ulcerative colitis—patients' and physicians' view. *Inflamm Bowel Dis.* 2021;27(11):1747-1755. **3.** VELSIPITY (etrasimod) Summary of Product Characteristics. Brussels, Belgium: Pfizer Europe Marketing Authorisation (MA) European Economic Interest Group (EEIG); [Month] 2023. **4.** Data on file. Pfizer Inc. **5.** What is an electrocardiogram (ECG)? British Heart Foundation website. <https://www.bhf.org.uk/information-support/heart-matters-magazine/medical/tests/electrocardiogram-ecg>. Accessed November 13, 2023. **6.** Sandborn WJ, Vermeire S, Peyrin-Biroulet L, et al. Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomised, double-blind, placebo-controlled, phase 3 studies [published correction appears in *Lancet.* 2023;401(10381):1000]. *Lancet.* 2023;401(10383):1159-1171.

[SmPC]