Velsipity® (etrasimod) 2mg tablets

GETTING STARTED

For adults with moderate to severe ulcerative colitis (UC)

Your doctor will request the following **screening tests** to determine if VELSIPITY is an appropriate treatment for you and to establish a baseline to monitor for changes in certain aspects of your health throughout treatment.

☐	**Blood Work**	Complete blood count (CBC) with differential and liver function tests. The CBC will check your white blood cells since they're important if you have to fight off an infection. The liver function tests will show how well your liver is working	**Before starting treatment**
☐	**ECG**	An initial ECG (electrocardiogram) to rule out any preexisting heart conditions you might not know about	**Before starting treatment**
☐	**Eye Exam**	Obtain baseline evaluation of the fundus, including the macula, so your doctor can monitor any changes in your eye health. There is an increased risk of certain eye conditions when taking medicines like VELSIPITY	**Near the start of your treatment**
☐	**Skin Exam**	It's important to establish a baseline to identify any suspicious skin lesions. If you've already had a skin exam this year, you may not need another one	**Near the start of your treatment**

It's also important to

- ☐ Review **vaccination records** to ensure immunizations are up to date with current guidelines
- ☐ Review a list of current or prior **medications, vitamins, and herbal supplements** to discuss with your doctor prior to starting treatment

Monitoring for and management of certain safety signals is recommended; there is no required scheduled monitoring

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PATIENT SUPPORT PROGRAM

Your **Dedicated Care Coordinator** (DCC) can explain insurance coverage and check for eligible savings. In addition, if eligible and requested by your Health Care Provider, your DCC may be able to schedule certain tests at home and/or in your doctor's office*

*Eligibility required. Commercially insured patients only. Baseline assessment coordination services are not available for patients enrolled in a state or federally funded health insurance program, or for patients who reside in MI, MN, or RI.

Scan the code to get started

velsipity.com/savings-and-support

IMPORTANT SAFETY INFORMATION

Do not take VELSIPITY if you:

- have had a heart attack, chest pain (unstable angina), stroke or mini stroke (transient ischemic attack or TIA), and certain types of heart failure requiring hospitalization in the last 6 months
- have or have had a history of unusual heartbeats (arrhythmia) that is not corrected by a pacemaker

Talk to your healthcare provider before taking VELSIPITY if you have any of these conditions or do not know if you have any of these conditions.

VELSIPITY can cause serious side effects, including:

- **Infections:** VELSIPITY can increase your risk of serious infections. These infections can be life-threatening and cause death. VELSIPITY lowers the number of white blood cells (lymphocytes) in your blood. This usually returns to normal within 4 to 5 weeks after you stop taking VELSIPITY. Your healthcare provider will test your blood before you start taking VELSIPITY. Your healthcare provider may delay or stop your VELSIPITY treatment if you have an infection. Call your healthcare provider right away if you have any of these symptoms of an infection during treatment with VELSIPITY, and for 5 weeks after you stop taking VELSIPITY: fever or high temperature, pain when peeing or peeing more often than usual as these can be signs of a urinary tract infection, tiredness, flu-like symptoms, or headache with fever, neck stiffness, sensitivity to light, nausea, or confusion as these may be symptoms of meningitis, an infection of the lining around your brain and spine.

Click for the full **Prescribing Information** and **Medication Guide**, also available at **velsipityPI.com**.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Slow heart rate (also known as bradyarrhythmia) when you start taking VELSIPITY:** VELSIPITY may cause your heart rate to temporarily slow down especially after you take your first dose. You will have a test called an electrocardiogram (ECG) to check the electrical activity of your heart before you take your first dose of VELSIPITY. Call your healthcare provider if you experience these symptoms of slow heart rate: feeling dizzy, feeling lightheaded, feeling like your heart is beating slowly or skipping beats, feeling short of breath, feeling confused, feeling tired, or chest pain.

Before taking VELSIPITY, tell your healthcare provider about all of your medical conditions, including if you:

- have a serious infection or an infection that does not go away or that keeps coming back (chronic).
- are unable to fight infections due to a disease.
- have received a vaccine in the past 4 weeks or are scheduled to receive a vaccine. You should be brought up to date with all age-required vaccines before starting treatment with VELSIPITY. VELSIPITY may affect how well a vaccine works. Tell your healthcare provider that you are receiving treatment with VELSIPITY before receiving a vaccine.
- have chickenpox or received the vaccine for chickenpox. Your healthcare provider may do a blood test for the chickenpox virus. You may need to get the full course of the chickenpox vaccine and then wait 4 weeks before you start taking VELSIPITY.
- have a slow heart rate.
- have an irregular or abnormal heartbeat (arrhythmia).
- have heart disease, Class I or II heart failure, history of a heart attack, high blood pressure or uncontrolled high blood pressure.
- have cerebrovascular disease or history of a stroke or ministroke.
- history of repeated fainting.
- have or have had liver problems.
- have or have had skin cancer.
- have breathing problems, including untreated sleep apnea.
- are pregnant or plan to become pregnant. VELSIPITY may harm your unborn baby. Talk with your healthcare provider if you are pregnant or plan to become pregnant. If you are a female who can become pregnant, talk with your healthcare provider and use effective birth control during your treatment with VELSIPITY and for 7 days after you stop taking VELSIPITY. If you become pregnant while taking VELSIPITY or within 7 days after you stop taking VELSIPITY, talk with your healthcare provider and enroll in the VELSIPITY Pregnancy Registry by calling 1-800-616-3791.
- are breastfeeding or plan to breastfeed. It is not known if VELSIPITY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take VELSIPITY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using VELSIPITY with other medicines can cause serious side effects. Especially tell your healthcare provider if you take or have taken:

- medicines to control your heart rhythm (antiarrhythmics), heartbeat, or blood pressure. These may be called beta blockers or calcium channel blockers.
- medicines that affect your immune system.
- certain medicines known as moderate to strong inhibitors of both CYP2C9 and CYP3A4, medicines such as fluconazole. If you are taking fluconazole, you should not take VELSIPITY.
- Rifampin. If you are taking rifampin, you should not take VELSIPITY.

You should not receive **live** vaccines at least 4 weeks before starting VELSIPITY, during treatment with VELSIPITY and for 5 weeks after you stop taking VELSIPITY. Talk to your healthcare provider before you receive a vaccine during treatment and for 5 weeks after treatment with VELSIPITY. If you receive a live vaccine, you may get the infection the vaccine was meant to prevent. Vaccines may not work as well when given during treatment with VELSIPITY.

VELSIPITY can cause serious side effects, including:

- **Liver problems.** VELSIPITY may cause liver problems. Your healthcare provider will do blood tests to check your liver before you start taking VELSIPITY. Call your healthcare provider right away if you have any of the following symptoms: unexplained nausea, vomiting, stomach area (abdominal pain), tiredness, loss of appetite, yellowing of the whites of your eyes or skin, or dark-colored urine.

- **Increased blood pressure.** Your healthcare provider should check your blood pressure during treatment with VELSIPITY and treat you as needed.

- **A problem with your vision called macular edema.** Your healthcare provider should test your vision around the time you start taking VELSIPITY or at any time you notice vision changes during your treatment with VELSIPITY. Call your healthcare provider right away if you have any of the following symptoms: blurriness or shadows in the center of your vision, sensitivity to light, a blind spot in the center of your vision, or unusually colored vision.

- **Types of skin cancer.** Certain types of skin cancer have happened with medicines in the same class as VELSIPITY. Limit the amount of time you spend in sunlight and ultraviolet (UV) light while taking VELSIPITY. Wear protective clothing and use a sunscreen with a high sun protection factor. Tell your healthcare provider if you have any changes in the appearance of your skin.

- **Swelling and narrowing of the blood vessels in your brain.** A condition called Posterior Reversible Encephalopathy Syndrome (PRES) has happened with drugs in the same class. Symptoms of PRES usually get better when you discontinue treatment. If not treated, PRES may cause a stroke. Call your healthcare provider right away if you have any of the following symptoms: sudden severe headache, sudden confusion, sudden loss of vision or other changes in your vision, or seizure. If you develop any of these symptoms, your healthcare provider will stop treatment with VELSIPITY.

- **Breathing problems.** Some people who take medicines in the same class as VELSIPITY may experience shortness of breath. Your healthcare provider may do tests to check your breathing during treatment with VELSIPITY. Call your healthcare provider right away if you have new or worsening breathing problems.

The most common side effects of VELSIPITY include headache, elevated liver tests, and dizziness. These are not all of the possible side effects of VELSIPITY. For more information, ask your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Pfizer at 1-800-438-1985.

USE/INDICATION

VELSIPITY is a prescription medicine used to treat adults with moderately to severely active ulcerative colitis. It is not known if VELSIPITY is safe and effective in children.

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Click for the full **Prescribing Information** and **Medication Guide**, also available at **velsipityPI.com**.

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