



Patient Safety Information Leaflet

Your name: _____

Prescriber's name: _____

Prescriber's phone number: _____

VELSIPITY™ start date: _____

VELSIPITY is used to treat adult patients with moderately to severely active ulcerative colitis (UC). It is used when a patient's UC is still active after other treatments have not worked or were not tolerated.

Safety information for patients taking VELSIPITY

- This leaflet contains important safety information you should be aware of before starting, during, and after treatment with VELSIPITY.
- For more information, read the Patient Medication Information leaflet included in each pack of VELSIPITY.
- If any of the information is not clear, ask your doctor or pharmacist any questions you may have.

Keep this leaflet with you and show it to any healthcare professional involved in your medical care – for example, your pharmacist or an emergency doctor.

! Safety information

Do not use VELSIPITY if you:

- are allergic to etrasimod or any of the other ingredients in VELSIPITY
- have an increased risk of infection because:
 - you have a condition that weakens your immune system
 - you take a medicine or receive a treatment that weakens your immune system
- have had a heart attack, chest pain, a stroke or mini-stroke, or certain types of severe heart failure in the last 6 months
- have certain types of irregular or abnormal heartbeats (arrhythmia)
- have a severe active infection or active chronic infection
- have cancer
- are pregnant or a woman of childbearing potential not using effective birth control
- are breastfeeding

Before taking VELSIPITY, talk to your healthcare professional about any health conditions or problems you may have, including the topics listed below

Talk to your doctor if you have:

- a slow heart rate or you are taking or have recently taken medicines that slow your heart rate
- had symptoms of a slow heart rate such as dizziness, tiredness, confusion, or fainting
- recently taken medicines to support a better impulse of your heartbeat such as beta blockers or calcium channel blockers
- an irregular heart rhythm (unless you have a working pacemaker)
- episodes of sudden loss of consciousness known as fainting
- untreated sleep apnea
- ever had a stroke or other diseases related to blood vessels in the brain
- reduced blood flow to your heart, have ever had a heart failure, or have ever had a heart attack
- problems with your liver
- an infection
- low levels of a type of white blood cell called lymphocytes
- recently had or are planning to have a vaccination (VELSIPITY may cause vaccines to be less effective)
- had problems with your vision
- inflammation of the eye
- diabetes
- high blood pressure
- severe lung disease (such as pulmonary fibrosis, asthma, or chronic obstructive pulmonary disease)
- a fever or high temperature

Serious side effects and what to do about them

All the possible side effects you may feel when taking VELSIPITY are not listed in this leaflet. If you experience any side effects not listed here, contact your healthcare professional.

The side effects of VELSIPITY may include:

- High level of cholesterol
- Headache
- Nausea



Talk to your healthcare professional if you experience any of the following serious side effects:

VERY COMMON	Infections Symptoms include: fever, chills, headache, feeling very tired, flu-like symptoms, nausea, swollen lymph nodes Lymphopenia (decreased white blood cells) Symptoms include: fever, cough, mouth ulcers, get infections more easily
COMMON	Urinary tract infection Symptoms include: pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine Bradycardia (slow heartbeat) Symptoms include: dizziness, tiredness, confusion, fainting, feeling lightheaded, feeling like your heart is beating slowly or skipping beats, shortness of breath, chest pain Hypertension (high blood pressure) Symptoms include: blurry vision, feeling lightheaded, feeling short of breath, measured high blood pressure, sometimes with headache or nosebleed Headache Feeling dizzy
RARE	Macular edema (a vision problem) Symptoms include: blurriness or shadows in the centre of your vision, feeling sensitive to light, a blind spot in the centre of your vision, colours look unusual Irregular heartbeat Symptoms include: feeling dizzy or fainting, chest pain, feeling short of breath, feeling like your heart is beating faster, feeling like you might throw up Breathing problems Symptoms include: shortness of breath Liver problems Symptoms include: yellowing of your skin or the whites of your eyes, abnormally dark urine, unexplained nausea or vomiting, tiredness, upper abdominal pain, loss of appetite Skin cancer Symptoms include: skin lesions or moles that appear, or if existing skin lesions change appearance



Stop VELSIPITY and get immediate medical help if you experience any of the following serious side effects:

FREQUENCY UNKNOWN	Posterior reversible encephalopathy syndrome (PRES, swelling and narrowing of blood vessels in your brain) Symptoms include: sudden severe headache, feeling nauseous or throwing up, confusion, drowsiness, personality change, paralysis, abnormal speech, convulsions, vision changes Progressive multifocal leukoencephalopathy (PML, a serious brain infection) Symptoms include: vision problems, weakness in the arms or legs that gets worse, clumsiness, lack of coordination, memory loss or confusion, problems speaking, personality changes
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Serious side effects and what to do about them (cont'd.)

If you have a troublesome symptom or side effect that isn't listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

For more information about **side effects**, please see **the back** of this leaflet.

Other warnings you should know about

Slow heart rate and heart problems:

Before you start taking VELSIPIITY, your healthcare professional will check your heart using a test called an electrocardiogram (ECG) to check if you have any heart problems. This is because when you start taking VELSIPIITY, your heart rate might decrease, or the impulse of your heartbeat might decrease.

Talk to your healthcare professional if you get any symptoms of bradycardia (slow heart rate). These include: dizziness, tiredness, confusion, fainting, feeling lightheaded, feeling like your heart is beating slowly or skipping beats, shortness of breath, or chest pain. You might also experience a slow heart rate and not have any symptoms.

Your healthcare professional might also check your blood pressure while you are taking VELSIPIITY. This is because VELSIPIITY can increase your blood pressure.

Infections:

Before you start taking VELSIPIITY, tell your healthcare professional if you have an infection. You must not take VELSIPIITY if you have a severe active infection or an active chronic infection.

VELSIPIITY lowers the number of white blood cells in your blood. This can increase your risk of getting an infection. This includes serious infections that can be life-threatening and cause death. You are more likely to get an infection while you are taking VELSIPIITY and for 5 weeks after you stop taking it.

Your healthcare professional may test your white blood cell levels before you start taking VELSIPIITY. Talk to your healthcare professional right away if you get any symptoms of an infection while you are taking VELSIPIITY and for 5 weeks after you stop taking it. These include: fever, chills, headache, feeling very tired, flu-like symptoms, nausea, or swollen lymph nodes. Your healthcare professional might stop or pause your treatment with VELSIPIITY if you get an infection.

Cancer:

Before you take VELSIPIITY, tell your healthcare professional if you have cancer. You must not take VELSIPIITY if you have cancer. Before you start taking VELSIPIITY or soon after you start taking it, your healthcare professional may examine your skin. Your skin may be looked at by your healthcare professional from time to time to look for any skin lesions or moles, especially if you have risk factors for skin cancer. If you find a mole, contact your healthcare professional right away so that they can look at it.

Limit how much time you spend in the sun by wearing clothes that protect your skin and by using sunscreen with a high protection factor (also known as SPF).

Progressive multifocal leukoencephalopathy (PML):

PML is a serious viral brain infection that may lead to severe disability or death. Cases of PML have been reported with medicines similar to VELSIPIITY. Symptoms of PML include vision problems, weakness in the arms or legs that gets worse, clumsiness, lack of coordination, memory loss or confusion, problems speaking, and personality changes.

If you get any of these symptoms, talk to your healthcare professional right away. If your healthcare professional thinks you might have PML, they will examine you further and may stop your treatment with VELSIPIITY.

Posterior reversible encephalopathy syndrome (PRES):

Rare cases of PRES have been observed in similar medicines as VELSIPIITY. During treatment with VELSIPIITY, if you develop any possible symptoms of PRES, speak to your healthcare professional right away. Symptoms include: sudden severe headache, feeling nauseous or throwing up, confusion, drowsiness, personality change, paralysis, abnormal speech, convulsions, and vision changes.

If you experience any of these symptoms, your healthcare professional should urgently examine how your brain is functioning, as these symptoms may be due to a condition called posterior reversible encephalopathy syndrome (PRES). If untreated, PRES may result in a stroke or bleeding in the brain. If your healthcare professional thinks you might have PRES, they will stop your treatment with VELSIPIITY.

Testing and monitoring:

Before and while you are taking VELSIPIITY, your healthcare professional may check your ability to breathe. They will also perform various blood tests and interpret the results.

Pregnancy and birth control:

You must not take VELSIPIITY if you are pregnant or are planning to become pregnant. This is because VELSIPIITY can harm an unborn baby. Your healthcare professional will explain the pregnancy risks to you before you start taking VELSIPIITY. They will ask you to do a pregnancy test to make sure that you are not pregnant. Your healthcare professional will give you a card which explains why you should not become pregnant while taking VELSIPIITY. It also explains what you should do to avoid getting pregnant while you are taking VELSIPIITY. You must use effective birth control while you are taking VELSIPIITY and for 6 days after you stop taking it. Talk to your healthcare professional about effective birth control methods.

Pregnancy registry: There is a pregnancy exposure registry for women who take VELSIPIITY while they are pregnant. The purpose of this registry is to collect information about the health of you and your baby. If you do become pregnant while taking VELSIPIITY, talk to your healthcare professional about participating in this registry. You may also call 1-800-616-3791 for more information.

Breastfeeding:

Do not take VELSIPIITY if you are breastfeeding. This is because VELSIPIITY may pass into breast milk.

Driving and using machines:

VELSIPIITY may cause dizziness, which can affect your ability to drive and use machines.

Other warnings you should know about (cont'd.)

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with VELSIPITY:

- Medicines used to control your heart rate and blood pressure, such as beta blocker medicines and calcium channel blocker medicines
- Medicines used to control your heart rhythm or heartbeat such as quinidine, procainamide, amiodarone, and sotalol
- Medicines that affect your immune system, including cancer treatment
- Vaccines
- Fluconazole, used to treat fungal infections, and other medicines that affect a certain enzyme in your body can increase the levels of VELSIPITY in the blood. These are not recommended to be taken in combination with VELSIPITY.
- Rifampicin, used to treat bacterial infections, and other medicines that affect a certain enzyme in your body can decrease the levels of VELSIPITY in the blood. These are not recommended to be taken in combination with VELSIPITY.
- Gemfibrozil, used to treat high cholesterol, and other medicines that affect an enzyme in the body can increase the levels of VELSIPITY in the blood for some patients. In these patients, these medicines are not recommended to be taken in combination with VELSIPITY.
- Itraconazole, used to treat fungal infections, and other medicines that affect an enzyme in the body can increase the levels of VELSIPITY in the blood for some patients. In these patients, these medicines are not recommended to be taken in combination with VELSIPITY.

PrVELSIPITY™ (etrasimod) ▼ Pregnancy reminder for childbearing individuals

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. For further information, see section on reporting side effects.

Version: 271038

Date of approval: February 2024

Patient information

If used during pregnancy, etrasimod can harm the unborn baby. Potential risks include loss of the unborn baby and birth defects.

- Do not use etrasimod if you are pregnant or breastfeeding or could become pregnant and are not using effective contraception.
- Before starting treatment with etrasimod:
 1. Your prescriber will explain the potential risks to an unborn baby if you become pregnant while taking etrasimod and will regularly inform you how to minimize the risks.
 2. You must use effective contraception while taking etrasimod and for 6 days after you stop taking etrasimod.
 3. Your doctor will carry out a pregnancy test and it must be negative. Pregnancy tests will also be checked during treatment.
- Tell your doctor immediately if you become pregnant during treatment with etrasimod or for 6 days after you stop taking it. Your doctor will discuss the risk of harmful effects to the baby associated with treatment and may arrange further tests such as an ultrasound. Etrasimod must be stopped during pregnancy.
- Tell your doctor right away if you are pregnant or breastfeeding, think you might be pregnant, or are planning to have a baby, including 6 days after you stop taking etrasimod.
- Keep this card with you and show it to any doctor or pharmacist involved in your care.
- See the VELSIPITY package leaflet for more information.

Reporting side effects

The safety of etrasimod is being closely monitored as it is a new medicine. It is important that any side effects should be reported, even those not listed in the Patient Medication Information leaflet that comes with the pack. You can help others by providing more information on the safety of your medication by reporting side effects.

Please report suspected adverse drug reactions to 1-866-234-2345 or by visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax.

Other information (please complete)

Patient's name: _____

Doctor's name: _____

Doctor's phone: _____

Doctor's fax: _____

If you stop taking VELSIPITY, keep this card with you for at least 2 months after taking the last dose of VELSIPITY.

For more information, read the Patient Medication Information leaflet included in each pack of VELSIPITY.



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PP-V1A-CAN-0031-EN

