

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VELSIPITY **etrasimod (as etrasimod L-arginine)**

Read this carefully before you start taking etrasimod and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about etrasimod.

What is VELSIPITY used for?

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.

How does VELSIPITY work?

VELSIPITY helps reduce inflammation in the gut. It works by stopping certain white blood cells from reaching the lining of the gut.

What are the ingredients in VELSIPITY?

Medicinal ingredients: etrasimod (as etrasimod L-arginine)

Non-medicinal ingredients:

Tablet core contains magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate.

Tablet coating contains FD&C blue #1/brilliant blue FCF aluminum lake, FD&C blue #2/indigo carmine aluminum lake, FD&C yellow #5/tartrazine aluminum lake, macrogol 4000 JP/PEG 3350, polyvinyl alcohol (partially hydrolyzed), talc, and titanium dioxide.

VELSIPITY comes in the following dosage forms:

Tablet, 2 mg etrasimod (as etrasimod L-arginine)

Do not use VELSIPITY if:

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

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VELSIPITY. Talk about any health conditions or problems you may have, including if you:

- have a slow heart rate or you are taking or have recently taken medicines that slow your heart rate.

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

Other warnings you should know about:

Slow heart rate and heart problems: Before you start taking VELSIPTTY, 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 VELSIPTTY, 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, 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 VELSIPTTY. This is because VELSIPTTY can increase your blood pressure.

Infections: Before you start taking VELSIPTTY, tell your healthcare professional if you have an infection. You must not take VELSIPTTY if you have a severe active infection or an active chronic infection. VELSIPTTY 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 VELSIPTTY and for 5 weeks after you stop taking it. Your healthcare professional may test your white blood cell levels before you start taking VELSIPTTY. Talk to your healthcare professional right away if you get any symptoms of an infection while you are taking VELSIPTTY and for 5 weeks after you stop taking it. These include: fever, chills, headache, feeling very tired, flu-like symptoms, nausea, swollen lymph nodes. Your healthcare professional might stop or pause your treatment with VELSIPTTY if you get an infection.

Cancer: Before you take VELSIPTTY, tell your healthcare professional if you have cancer. You must not take VELSIPTTY if you have cancer. Before you start taking VELSIPTTY 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 VELSIPITY. 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 straight away. If your healthcare professional think you might have PML, they will examine you further and may stop your treatment with VELSIPITY.

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

Testing and monitoring: Before and while taking VELSIPITY, your healthcare professional may check your ability to breathe. They will also perform various blood tests and will interpret the results.

Pregnancy and birth control: You must not take VELSIPITY if you are pregnant or are planning to become pregnant. This is because VELSIPITY can harm an unborn baby. Your healthcare professional will explain the pregnancy risks to you before you start taking VELSIPITY. 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 VELSIPITY. It also explains what you should do to avoid getting pregnant while you are taking VELSIPITY. You must use effective birth control while you are taking VELSIPITY 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 VELSIPITY 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 VELSIPITY, talk to your healthcare professional. Talk to them about participating in this registry. You may also call 1-800-616-3791 for more information.

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

Driving and using machines: VELSIPITY may cause dizziness, which can affect your ability to drive and use machines.

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 certain other medicines that affect a certain 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 certain other medicines that affect a certain 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.

How to take VELSIPITY:

- Always take VELSIPITY exactly as your healthcare professional tells you to.
- Swallow tablets whole with water. Do not split, crush, or chew the tablets.
- You can take VELSIPITY with or without food.
- Check with your healthcare professional if you are not sure how to take VELSIPITY.

Usual adult dose:

Take one tablet once a day.

Overdose:

If you think you, or a person you are caring for, have taken too much VELSIPITY, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of VELSIPITY, take it as soon as you remember on that day. If you forget to take VELSIPITY for the whole day, skip the missed dose. Take the next scheduled dose the following day. Do not take a double dose to make up for a forgotten dose.

Contact your healthcare professional to discuss how to restart taking VELSIPITY if:

- You miss a dose for more than 2 days in a row within your first week of taking it or;
- If you miss a dose for more than 7 days in a row at any point.

What are possible side effects from using VELSIPITY?

These are not all the possible side effects you may have when taking VELSIPITY. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- high level of cholesterol in the blood
- headache
- nausea

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Infection: fever, chills, headache, feeling very tired, flu-like symptoms, nausea, swollen lymph nodes.		X	
Lymphopenia (decreased white blood cells):fever, cough, mouth ulcers, get infections more easily.		X	
COMMON			
Urinary tract infection: pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine.		X	
Bradycardia (slow heartbeat): dizziness, tiredness, confusion, fainting, feeling lightheaded, feeling like your heart is beating slowly or skipping beats, shortness of breath, chest pain.		X	
Hypertension (high blood pressure): blurry vision, feeling lightheaded, feeling short of breath, measured high blood pressure, sometimes with headache or nosebleed.		X	
Headache		X	
Feeling dizzy		X	
RARE			
Macular edema (a vision problem): blurriness or shadows in the center of your vision, feeling sensitive to		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
light, a blind spot in the center of your vision, colors look unusual.			
Irregular heartbeat: feeling dizzy or fainting, chest pain, feeling short of breath, feeling like your heart is beating faster, feeling like you might throw up.		X	
Breathing problems: shortness of breath		X	
Liver problems: yellowing of your skin or the whites of your eyes, abnormally dark urine, unexplained nausea or vomiting, tiredness, upper abdominal pain, loss of appetite.		X	
FREQUENCY UNKNOWN			
Posterior Reversible Encephalopathy Syndrome (PRES, swelling and narrowing of blood vessels in your brain): sudden severe headache, feeling nauseous or throwing up, confusion, drowsiness, personality change, paralysis, abnormal speech, convulsions, vision changes.			X
Progressive multifocal leukoencephalopathy (PML, a serious brain infection): vision problems, weakness in the arms or legs that gets worse, clumsiness, lack of coordination, memory loss or confusion, problems speaking, personality changes.			X
Skin cancer: skin lesions or moles that appear or if existing skin lesions change appearances.		X	

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

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada 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; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store VELSIPITY at room temperature (15°C to 30°C). Keep out of reach and sight of children.

If you want more information about VELSIPITY:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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