

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using VELSIPITY?

VELSIPITY contains the active ingredient etrasimod. VELSIPITY is used to treat ulcerative colitis (UC). It is used when a patient's UC is still active after other medicines have not worked or were not tolerated.

For more information, see Section [1. Why am I using VELSIPITY?](#) in the full CMI.

2. What should I know before I use VELSIPITY?

Do not use if you have ever had an allergic reaction to etrasimod or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VELSIPITY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VELSIPITY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VELSIPITY?

- The recommended dose of VELSIPITY is one 2 mg tablet taken once a day
- VELSIPITY should be swallowed whole and can be taken with or without food

More instructions can be found in Section [4. How do I use VELSIPITY?](#) in the full CMI.

5. What should I know while using VELSIPITY?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist, or optometrist you visit that you are taking VELSIPITY.• Use effective contraception while taking VELSIPITY. Tell your doctor if you become pregnant.• Contact your doctor immediately if you notice changes in your skin or vision, or experience a severe headache, dizziness or if you develop any signs or symptoms of an infection.• Check with your doctor before receiving any vaccinations.• Make regular appointments to monitor your skin and blood pressure and check your blood results.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not give your medicine to anyone else, even if they have the same condition as you.• Do not breastfeed while taking VELSIPITY.
Driving or using machines	<ul style="list-style-type: none">• VELSIPITY may cause dizziness in some people.• Be careful before you drive or use any machines or tools until you know how VELSIPITY affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store tablets below 30°C.

For more information, see Section [5. What should I know while using VELSIPITY?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Common (less serious) side effects include headache and dizziness. More serious side effects include serious infections (e.g., urinary tract), slow or irregular heartbeat, high blood pressure, low white blood cells disturbance or loss of vision, progressive weakness, clumsiness, memory loss or confusion, severe headache, seizures (fits).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VELSIPITY®

Active ingredient(s): *etrasimod*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VELSIPITY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VELSIPITY.**

Where to find information in this leaflet:

1. [Why am I using VELSIPITY?](#)
2. [What should I know before I use VELSIPITY?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use VELSIPITY?](#)
5. [What should I know while using VELSIPITY?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using VELSIPITY?

VELSIPITY contains the active ingredient etrasimod. VELSIPITY is a sphingosine 1-phosphate (S1P) receptor modulator.

VELSIPITY is used to treat moderately to severely active ulcerative colitis (inflammation of the large bowel) in adults who have not responded or had an intolerance to other medicines also used to treat ulcerative colitis.

2. What should I know before I use VELSIPITY?

Warnings

Do not use VELSIPITY if:

- you are allergic to etrasimod, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- in the last 6 months, you have had a heart attack, unstable angina, stroke, or certain types of heart failure.
- you have irregular or abnormal heartbeat (arrhythmia).

Check with your doctor if you:

- have a history of heart disease, heart attack, heart failure, irregular heartbeat, stroke, or uncontrolled high blood pressure;
- have an active infection, or have a lowered immune system (due to a disease or because you take medicines that lower your immunity);
- recently had or are planning to have a vaccination, as it is recommended that you do this at least 4 weeks before starting treatment with VELSIPITY;

- have not had chickenpox or not been vaccinated against chickenpox;
- have had any eye or vision problems. Your doctor will arrange an eye examination before you start treatment with VELSIPITY if you have a history of diabetes or eye conditions such as uveitis or retinal disease;
- have severe lung disease, such as pulmonary fibrosis, asthma or chronic obstructive pulmonary disease;
- have a fever or high temperature;
- have low levels of white blood cells called lymphocytes
- have cancer;
- have problems with your liver. VELSIPITY is not recommended if you have severe liver problems. Your doctor will check your liver function before you start treatment with VELSIPITY;
- have progressive multifocal leukoencephalopathy (PML). PML is a rare viral brain infection that may lead to severe disability or death. PML symptoms include disturbance of vision, progressive weakness, clumsiness, memory loss or confusion;
- have Posterior reversible encephalopathy syndrome (PRES, swelling and narrowing of blood vessels in your brain): sudden severe headache, feeling like you might throw up or throwing up, confusion, drowsiness, personality change, paralysis, abnormal speech, convulsion, vision changes
- have any other medical conditions;.
- take any medicines for any other condition;
- drive or use machine. VELSIPITY may cause dizziness, which can affect your ability to drive and use machines

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

First dose monitoring

If you have certain heart conditions, your doctor will also monitor you for at least the first 4 hours after your first dose. Your doctor will ask you to stay at the hospital or clinic for 4 hours and will measure your pulse and blood pressure every hour after taking the first dose of Velsipity. You should have an electrocardiogram (ECG) performed before the first dose of Velsipity and after the 4-hour monitoring period. If after the 4-hour period you have a very slow or decreasing heart rate, or if your ECG shows abnormalities, you may need to be monitored for a longer period until these have resolved.

Pregnancy and breastfeeding

There is potentially a serious risk to your baby if you are taking VELSPITY while you are pregnant. Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is unknown whether VELSPITY is excreted in breast milk. You should not breastfeed while taking VELSPITY.

Contraception

You should use effective contraception to avoid becoming pregnant while using VELSPITY and for 10 days after you stop using it.

Sun protection

Skin cancers have been reported with medicines similar to VELSPITY. Talk to your doctor straight away if you develop changes with your skin. Since there is a risk for skin cancer, you should have periodic skin examinations and limit your exposure to sun light and UV (ultraviolet) light, by wearing protective clothing and applying regular sunscreen (with high sun protection factor (SPF)).

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VELSPITY and affect how it works.

- Medicines that regulate your heartbeat such as quinidine, procainamide, amiodarone, or sotalol.
- Medicines that reduce your heartbeat.

Before you start taking VELSPITY, 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 VELSPITY, your heart rate 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 VELSPITY. This is because VELSPITY can increase your blood pressure.

- Medicines that reduce your immune system such as chemotherapy agents, or other medicines used to treat ulcerative colitis.
- Vaccinations may be less effective while you are using VELSPITY and for up to 2 weeks after stopping it. Live vaccines may also carry the risk of infection and should be avoided during treatment with VELSPITY and for 2 weeks after stopping treatment.

Medicines that may increase the effect of VELSPITY include:

- CYP2C9 and CYP3A4 inhibitors e.g., fluconazole used to treat fungal infections.

Medicines that may reduce the effect of VELSPITY include:

- CYP2C8, CYP2C9 and CYP3A4 inducers e.g., rifampicin used to treat bacterial infections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VELSPITY.

4. How do I use VELSPITY?

How much to take

- The recommended dose of VELSPITY is one 2 mg tablet taken once a day.
- Follow the instructions provided and use VELSPITY until your doctor tells you to stop.

When and how to take VELSPITY

- VELSPITY should be taken once a day at about the same time each day.
- Swallow the tablets whole.
- VELSPITY can be taken with or without food in your stomach.
- Do not stop taking VELSPITY or change your dose without talking to your doctor.

If you forget to use VELSPITY

VELSPITY should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking VELSPITY as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much VELSPITY

If you think that you have used too much VELSPITY, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VELSIPITY?

Things you should do

- if you are of childbearing age, use effective contraception to avoid becoming pregnant including for 10 days after you stop treatment with VELSIPITY.
- have regular skin checks.
- tell your doctor before you receive any vaccine.
- monitor your blood pressure regularly.
- keep all your appointments so that your progress can be checked.
- limit your exposure to sunlight and UV light.

Call your doctor straight away if you:

- develop any signs or symptoms of an infection.
- experience any changes in your vision.
- notice any unusual spots or changes on your skin.
- develop a severe headache, feel confused or have seizures (fits) and loss of vision.

Remind any doctor, dentist or pharmacist you visit that you are using VELSIPITY.

Things you should not do

- do not stop taking this medicine suddenly or change your dose without talking to your doctor first.
- do not give your medicine to anyone, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VELSIPITY affects you.

VELSIPITY may cause dizziness in some people.

Looking after your medicine

- Store the tablets below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects and what to do about them			
Symptom/Effect	Talk to your healthcare professional		Stop taking medicine and get immediate help
	Only if severe	In all cases	
VERY COMMON			
Infection: fever, chills, headache, feeling very tired, flu-like symptoms, feeling like you might throw up, 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 when urinating, frequent urination, blood in urine, pain in the pelvis, strong-smelling urine, cloudy urine		x	
Bradycardia (slow heartbeat): dizziness, tiredness, confusion, fainting, feeling light-headed, feeling like your heart is beating slowly or skipping beats, shortness of breath, chest pain.		x	
Hypertension (high blood pressure): blurry vision, feeling light-headed, feeling short of breath, measure high blood pressure, sometimes with headache or nosebleed.		x	
Headache		x	
Feeling dizzy		x	
RARE			
Macular oedema (a vision problem): blurriness or shadows in the centre of your vision, feeling sensitive		x	

Side effects and what to do about them			
to light. A blind spot in the centre of your vision, colours 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 throwing up, 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 like you might throw up or throwing up, confusion, drowsiness, personality change, paralysis, abnormal speech, seizures (fits), vision changes.			x
Progressive multifocal leukoencephalopathy (PML, a serious brain infection): vision problems, weakness in 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 appearance.		x	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some of these side effects (high cholesterol, high blood pressure, irregular heartbeat, change in liver function, abnormal blood test results) can only be found when your doctor does blood tests from time to time to check your progress.

Call your doctor straight away if you develop any signs or symptoms of an infection and you have recently stopped taking VELSIPITY.

VELSIPITY may continue to work and cause side effects for up to 2 weeks after you stop taking it.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VELSIPITY contains

Active ingredient (main ingredient)	Etrasimod
Other ingredients (inactive ingredients)	Magnesium stearate Mannitol Microcrystalline cellulose Sodium starch glycollate type A Opadry® II Complete Film Coating System 85F110190-CN Green (ID: 144806)
Potential allergens	Tartrazine

Do not take this medicine if you are allergic to any of these ingredients.

VELSIPITY does not contain lactose, sucrose, or gluten.

What VELSIPITY looks like

VELSIPITY is supplied as a green, round, film-coated tablet, debossed with "ETR" on one side and "2" on the other side (AUST R 405529).

Who distributes VELSIPITY

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizermedinfo.com.au

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