Package leaflet: Information for the patient

Velsipity® 2 mg film-coated tablets
etrasimod

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, your doctor will give you a patient card, which contains important safety information that you need to be aware of. Keep this patient card with you.

What is in this leaflet

1. What Velsipity is and what it is used for
2. What you need to know before you take Velsipity
3. How to take Velsipity
4. Possible side effects
5. How to store Velsipity
6. Contents of the pack and other information

1. What Velsipity is and what it is used for

Velsipity contains the active substance etrasimod, which belongs to a group of medicines known as sphingosine-1-phosphate receptor modulators.

Velsipity is used in adults and adolescents aged 16 years and older for the treatment of moderately to severely active ulcerative colitis (UC). Ulcerative colitis is an inflammatory disease of the large bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or cannot take these medicines, you may be given Velsipity to reduce the signs and symptoms of the disease.

The active substance in Velsipity, etrasimod, prevents lymphocytes (a type of white blood cell) from travelling from the lymph nodes (part of the body's immune system that contains lymphocytes) into the blood. These lymphocytes are involved in the inflammation that is linked to the development of ulcerative colitis. By reducing the number of lymphocytes circulating in the blood surrounding the large bowel, etrasimod helps to reduce bowel inflammation and the symptoms associated with the disease.

2. What you need to know before you take Velsipity

Do not take Velsipity
- if you are allergic to etrasimod or any of the other ingredients of this medicine (listed in section 6);
- if your healthcare professional has told you that you have a severely weakened immune system;

- if you have had a heart attack, unstable angina pectoris (chest pain caused by interruptions in the heart's blood supply that occurs at rest or without an obvious trigger), stroke, transient ischaemic attack (TIA, also known as a mini-stroke) or certain types of severe heart failure in the last 6 months;
- if you have certain types of arrhythmia (irregular or abnormal heartbeat) – your doctor will check your heart before starting treatment;
- if you have a severe active infection or active chronic infection, such as hepatitis (inflammation of the liver) or tuberculosis;
- if you have cancer;
- if you have severe liver problems;
- if you are pregnant or a woman of childbearing potential not using effective contraception.

Warnings and precautions
Talk to your doctor or, pharmacist before taking Velsipity if:
- you have a slow heart rate or you are taking or have recently taken medicines that slow your heart rate (such as beta blockers or calcium channel blockers);
- you have ever had a stroke or other diseases related to blood vessels in the brain;
- you have problems with your liver;
- you have an infection;
- you have low levels of lymphocytes (a type of white blood cell);
- you have recently had or are planning to have a vaccination;
- you have ever had problems with your vision or other symptoms of build-up of fluid in the back of the eye;
- you have inflammation of the eye;
- you have diabetes (which can cause problems with your eyes);
- you have high blood pressure;
- you have severe lung disease, such as pulmonary fibrosis (lung damage with tissue scarring and thickening), asthma or chronic obstructive pulmonary disease (a type of lung disease marked by permanent damage to lung tissues).

Slow heart rate and irregular heart rhythm
Before you start taking Velsipity, your doctor will check your heart using an electrocardiogram (ECG; a test of the heart's electrical activity). This is because Velsipity can cause a temporary decrease in heart rate and other heart rhythm disorders when starting treatment. When this happens, you may feel dizzy or tired or be consciously aware of your heartbeat, or your blood pressure may drop. If these effects are severe, tell your doctor, because you may need treatment right away. If you restart treatment again after stopping for 7 or more days in a row, your doctor may re-check your heart using an ECG.

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 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.

High blood pressure
As Velsipity can increase your blood pressure, your doctor may want to check your blood pressure regularly.

Infections
Velsipity lowers the levels of white blood cell in your blood (particularly the lymphocyte count). White blood cells fight infection. While you are taking Velsipity (and for up to about 2 weeks after you stop taking it), you may be more likely to get infections, and any infection that you already have may get worse. Talk to your doctor if you develop an infection. If you think you have an infection,

have a fever, feel like you have the flu, have shingles or have a headache accompanied by a stiff neck, with sensitivity to light, nausea, rash, and/or confusion or seizures (fits) (these may be symptoms of meningitis and/or encephalitis caused by a fungal or herpes viral infection), contact your doctor straight away, because it could be serious and life-threatening.

Cases of progressive multifocal leukoencephalopathy (PML) have been reported with medicines similar to Velsipity. 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. If you develop any of these symptoms, speak to your doctor straight away. Your doctor will consider performing further tests to evaluate this condition and will stop your treatment with Velsipity if PML is confirmed.

Macular oedema
Velsipity can cause a problem with your vision called macular oedema (swelling of the macula, the central part of the retina at the back of the eye). The risk of developing macular oedema is higher if you have diabetes, uveitis (inflammation of the uvea, the layer beneath the white of the eyeball), or certain other eye problems. If you have any of these conditions, your doctor will check your vision before you start taking Velsipity and regularly during treatment. If you do not have these conditions, your doctor will check your vision within 3-4 months after starting treatment. Tell your doctor about any changes in your vision while on Velsipity.

Call your doctor straight away if you have any of the following:
- blurriness or shadows in the centre of your vision;
- a blind spot in the centre of your vision;
- sensitivity to light;
- unusually coloured (tinted) vision.

Cancer
Velsipity weakens your immune system. This increases your risk of developing cancers, in particular skin cancers. Skin cancers have been reported with medicines similar to Velsipity. Talk to your doctor straight away if you notice any skin nodules (e.g., shiny pearly nodules), patches or open sores that do not heal within weeks. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (e.g., unusual moles) with a change in colour, shape, or size over time. Since there is a risk for skin cancer, you should limit your exposure to sunlight and UV (ultraviolet) light by wearing protective clothing and regularly applying sunscreen (with high sun protection factor).

Posterior reversible encephalopathy syndrome (PRES)
Posterior reversible encephalopathy syndrome (PRES) is a condition where the brain swells. PRES symptoms include headache, changes in vision, reduced awareness, confusion, and seizures (fits). If you develop any of these symptoms, speak to your doctor straight away.

Vaccinations
If you need to receive a vaccine, seek your doctor’s advice first. Vaccines may not work as well as they should during your treatment with Velsipity. You are advised to make sure your vaccinations are up-to-date before you start treatment. So-called live vaccines may trigger the infection that they are supposed to prevent and should therefore be given at least 4 weeks before you start treatment, or at least 2 weeks after you stop taking Velsipity.

Liver function tests
Velsipity may affect your liver function. Tell your doctor straight away if you develop any of the following symptoms: yellowing of your skin or the whites of your eyes, abnormally dark urine (brown coloured), pain on the right side of your stomach area (abdomen), tiredness, feeling less hungry than usual or unexplained nausea and vomiting.

Before, during and after the treatment, your doctor will request blood tests to monitor your liver function.

Lung problems
Velsipity may have an effect on the lung function. Patients with severe lung problems have a higher chance of developing these side effects.

Other treatments for ulcerative colitis
Your doctor will usually advise that you stop other treatments for ulcerative colitis with the exception of corticosteroids (like cortisone), and mesalazine. Some medicines for ulcerative colitis may also be used for other conditions. Tell your doctor about all other medicines you take. When switching from the previous treatment, because of the risk of additive immunosuppressive effects, the risk of infection may be increased for some time. Do not take any other immunosuppressive products unless your doctor has told you to do so.

Women of childbearing potential
If used during pregnancy, Velsipity can harm the unborn baby. Before you start treatment with Velsipity, your doctor will explain the risk to you and ask you to do a pregnancy test in order to ensure that you are not pregnant. Your doctor will give you a patient card which explains why you should not become pregnant while taking Velsipity. It also explains what you should do to avoid becoming pregnant while you are taking Velsipity. You must use effective contraception during treatment and for at least 14 days after stopping treatment (see "Pregnancy, contraception, and breast-feeding" in section 2).

If any of these apply to you, tell your doctor or pharmacist before taking Velsipity.

Children and adolescents
Do not give this medicine to children and adolescents aged under 16 years. This is because Velsipity has not been studied in this age group.

Other medicines and Velsipity
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Velsipity can affect the way some other medicines work. Also, some other medicines can affect the way Velsipity works.

In particular, before taking Velsipity, tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:
- Medicines to control your heart rate and blood pressure (beta blocker medicines and calcium channel blocker medicines); use of these medicines could strengthen the effect of Velsipity on irregular heartbeat.
- Medicines to control your heart rhythm (antiarrhythmics), or heartbeat.
- Medicines that affect your immune system; use of these medicines with Velsipity could weaken the immune system.
- Vaccines; if you need to receive a vaccine, talk to your doctor. You should not take Velsipity for at least 2 weeks before a vaccination. You should not take Velsipity for at least 4 weeks after receiving a live vaccine.
- Fluconazole (an anti-fungal treatment) and certain other medicines can increase the levels of Velsipity in the blood, which increases the risk of side effects with Velsipity. It is recommended that you do not take these while also taking Velsipity and your doctor will advise you on this.
- Rifampicin, enzalutamide, and certain other medicines can decrease the levels of Velsipity in the blood, reducing its effectiveness. It is recommended that you do not take these while also taking Velsipity and your doctor will advise you on this.

Velsipity may slightly increase the levels of hormones released from some contraceptive pills. You will still be protected from pregnancy, but your chances of side effects from contraceptive pills may be higher. If you have any side effects, talk to your doctor or pharmacist.

Pregnancy, contraception, and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy and contraception
Do not use Velsipity during pregnancy, if you are trying to become pregnant, or if you are a woman who could become pregnant and you are not using effective contraception. If Velsipity is used during pregnancy, there is a risk of harm to the unborn baby. If you are a woman who could become pregnant, your doctor will inform you about this risk before you start treatment with Velsipity and will ask you to do a pregnancy test in order to ensure that you are not pregnant. You must use effective contraception while taking Velsipity and for at least 14 days after you stop taking it. Ask your doctor about reliable methods of contraception.

Your doctor will give you a patient card which explains why you should not become pregnant while taking Velsipity.

If you do become pregnant while taking Velsipity, tell your doctor straight away. Your doctor will likely stop treatment (see "If you stop taking Velsipity" in section 3) and pre-natal checks will be performed to monitor the health of the unborn baby.

Breast-feeding
You should not breast-feed while you are taking Velsipity. This is to avoid a risk of side effects for the baby since Velsipity may pass into breast milk.

Driving and using machines
Velsipity is not expected to have an influence on your ability to drive and use machines. You may, however, feel dizzy after taking Velsipity. If this happens, do not drive or use machines.

Velsipity contains tartrazine (E102)
The colouring agent in Velsipity contains tartrazine (E102), which may cause allergic reactions.

Velsipity contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Velsipity

Velsipity will be started under the supervision of a doctor who is experienced in treating ulcerative colitis. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How to take
- The recommended dose of Velsipity is one 2 mg tablet taken once daily.
- Take Velsipity with food for the first 3 days. After this, you can take Velsipity each day with or without food.
- Swallow the tablet whole with water. Do not split, crush, or chew the tablet before swallowing as it may change how much medicine gets into your body.

If you take more Velsipity than you should
If you have taken more Velsipity than you should, call your doctor straight away or go to a hospital straight away. Take the medicine pack and this package leaflet with you.

If you forget to take Velsipity
If you forget to take a dose of Velsipity, take the next dose at your usual time. Do not double the dose.

If you stop taking Velsipity
Do not stop taking Velsipity or change your dose without talking to your doctor first. If your doctor decides to pause your treatment for 7 days or more in a row, the medicine must be taken with food for the first 3 days after you restart taking Velsipity. After that you can take Velsipity with or without food.

If you restart Velsipity after stopping your treatment for 7 days or more in a row, the effect on heart rate that may be seen when treatment is first started may re-occur and you may need to be monitored at the hospital or clinic. Do not restart Velsipity after stopping it for more than 7 days without seeking advice from your doctor.

Velsipity will stay in your body for up to 14 days after you stop taking it. Your white blood cell count (lymphocyte count) may remain low for up to about 2 weeks and side effects described in this leaflet may still occur (see "Possible side effects" in section 4) during this period.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Tell your doctor or pharmacist immediately if you notice any of the side effects listed below, which could become serious:

Common (may affect up to 1 in 10 people)
- bradycardia (slow heart rate)
- hypertension (high blood pressure)
- urinary tract infection (infection of the parts of the body that collect and pass out urine)
- lower respiratory tract infection (infection of the lower airways or lungs)

Uncommon (may affect up to 1 in 100 people)
- atrioventricular block (a type of heart rhythm disorder)
- macular oedema (swelling in the macula, the central part of the retina at the back of the eye)

Other side effects
Tell your doctor or pharmacist immediately if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people)
- lymphopenia (low levels of lymphocytes, a type of white blood cell)

Common (may affect up to 1 in 10 people)
- hypercholesterolaemia (high blood cholesterol levels)
- headache
- feeling dizzy
- increased liver enzyme levels in blood tests, which can be a sign of problems with your liver function
- neutropenia (low levels of neutrophils, a type of white blood cell)
- visual impairment

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme

at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Velsipity

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle, blister, and carton after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special temperature storage conditions.
- Store in the original package in order to protect from moisture.
- Do not use this medicine if you notice any damage or signs of tampering with the pack.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Velsipity contains

- The active substance is etrasimod. Each film-coated tablet contains etrasimod arginine equivalent to 2 mg etrasimod.
- The other excipients are:

  Tablet core
  Magnesium stearate (E470b), mannitol (E421), microcrystalline cellulose (E460i), sodium starch glycolate (Type A)

  Tablet coating
  Brilliant blue FCF aluminium lake (E133), indigo carmine aluminium lake (E132), tartrazine aluminium lake (E102), macrogol 4000 (E1521), poly(vinyl alcohol) (E1203), talc (E553b), and titanium dioxide (E171)

What Velsipity looks like and contents of the pack
Velsipity 2 mg is a green, round, film-coated tablet of approximately 6 mm diameter with “ETR” on one side and “2” on the other side.

Pack sizes:

- Bottle of 30 film-coated tablets
- Blisters of 28 film-coated tablets
- Blisters of 98 film-coated tablets

Not all pack sizes may be marketed.

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