This guide has been developed by Pfizer and is intended only for patients who have been prescribed Velsipity®▼ (etrasimod) in the United Kingdom, or their caregivers.

Velsipity®▼(etrasimod)

Patient/Caregiver Guide

Important information about treatment with Velsipity® (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 www.mhra.gov.uk/yellowcard for how to report side effects.

Before you start taking etrasimod, read the patient information leaflet carefully as it has important information for you. Keep the leaflet as you may need to read it again while taking etrasimod.

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard and the free Yellow Card app, available from the Google Play Store or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

If you have any questions or require further information, please speak to your doctor or pharmacist.

This information does not replace the Patient Information Leaflet that comes with your medicine. Please read it carefully.

Pfizer

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What is Velsipity (etrasimod) and how does it work?

Velsipity is a medicine used for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

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

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.

As a patient with UC, you may have been given other medicines. If you did not respond well enough or cannot take those medicines, you may be given etrasimod to reduce the signs and symptoms of your disease.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not change your dose or stop taking etrasimod unless your doctor tells you to. Tell any doctor you see that you are being treated with etrasimod.

Do not take etrasimod if:

- You are allergic to etrasimod or any of the other ingredients of this medicine
- 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).

As part of your introduction to this medicine:

- Read the **Patient Information Leaflet** carefully. It has important information about taking etrasimod
- If you are a woman of childbearing potential, read the **Patient Card for Women of Childbearing Potential**, as it contains important information about the risk of taking etrasimod while pregnant

This information does not replace the Patient Information Leaflet that comes with your medicine. Please read it carefully.

Before taking etrasimod for the first time

Talk to your doctor or pharmacist if:

- You have a slow heart rate or you are taking or have recently taken medicines that can slow your heart rate
- 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 symptoms of build-up of fluid in the back of the eye
- You have inflammation of the eye(s)
- You have diabetes (which can cause problems with your eyes)
- You have high blood pressure
- You have severe lung disease, such as pulmonary fibrosis (a form of lung damage with tissue scarring and thickening), asthma or chronic obstructive pulmonary disease (also known as COPD, a lung disease that causes airflow blockage and permanent damage to lung tissues)

Heart monitoring

Heart monitoring is required because etrasimod can slow the heart rate or cause irregular rhythms.

- Your doctor will check your heart using an electrocardiogram before you start taking this medicine
- If you have certain heart conditions, your doctor will monitor you for at least the first 4 hours after your first dose to check for signs and symptoms of a slowing heart rate (symptomatic bradycardia), including dizziness. This may include hourly pulse and blood pressure checks. An electrocardiogram before and after the 4 hours may also be performed

- Make sure to report immediately any dizziness, vertigo, nausea, or palpitations when starting etrasimod. Caution should be taken with concomitant use of medicines that slow the heart rate
- Inform your doctor if your treatment with etrasimod is interrupted for 7 or more consecutive days, as you may need another electrocardiogram to check your heart before starting treatment again.

Visual symptoms

This medicine can cause macular oedema, which involves swelling in part of the retina (a light-sensitive layer of tissue at the back of your eye) and can lead to worsening of vision. Risk of macular oedema is higher if you have diabetes, inflammation of your eye (e.g. uveitis), or certain other eye problems. If you have these risks, your doctor should check your vision before you start taking this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking etrasimod. Before you start treatment, your doctor will:

- Explain to you the risk of taking this medicine while pregnant
- Ask you to do a pregnancy test to ensure you are not pregnant
- Give you a patient card which explains why you should not become pregnant while taking this medicine and what you should do to avoid becoming pregnant

Additionally, make sure you:

- Are using effective contraception while taking this medicine and for at least 14 days after you stop taking it (ask your doctor about reliable methods of contraception)
- Stop taking this medicine at least 14 days before pregnancy is planned
- Tell your doctor straight away if you do become pregnant while taking this medicine. Your doctor will stop treatment and pre-natal checks will be performed to monitor the health of the unborn baby
- Do not breastfeed while you are taking this medicine to avoid a risk of side effects for the baby as it may pass into breast milk

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After you start taking etrasimod

Blood pressure

Etrasimod may increase your blood pressure, so your doctor may want to check your blood pressure regularly.

Infections

While you are taking this medicine (and for up to 2 weeks after you stop taking it), you may be more likely to get infections. Any infection that you already have may get worse. If you experience any of the following, contact your doctor straight away, because these could be symptoms of more serious and potentially life-threatening conditions:

- Think you have an infection
- Have a fever
- Feel like you have the flu
- Have shingles
- Have a headache accompanied by a stiff neck, with sensitivity to light, nausea, rash, and/or confusion or seizures (fits)

Cases of progressive multifocal leukoencephalopathy, a rare brain infection that affects parts of the brain, have been reported with medicines similar to this one. 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.

Visual symptoms

Etrasimod 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 etrasimod 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 etrasimod.

Call your doctor straight away if you develop 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

Skin cancer

Skin cancers have been reported with medicines similar to etrasimod. Talk to your doctor straight away if you notice skin nodules (shiny pearly lumps), skin patches or open sores that do not heal within weeks. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (like unusual moles) with a change in colour, shape or size over time. You should limit your exposure to sunlight and ultraviolet light by wearing protective clothing and applying regular sunscreen (with high sun protection factor).

Neurological symptoms

During treatment with this medicine, if you have a severe headache, feel confused, have seizures (fits), or loss of vision, speak to your doctor straight away. These symptoms may be due to posterior reversible encephalopathy syndrome, a condition in which parts of the brain are affected by swelling.

Liver function

Tell your doctor straight away if you develop yellowing of your skin or on the whites of your eyes, abnormally dark urine (brown coloured), pain on the right side of your stomach area, tiredness, feeling less hungry than usual or unexplained nausea and vomiting.

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that comes with your medicine. Please read it carefully.

Pregnancy, contraception and breastfeeding

Do not use etrasimod if you are pregnant, if you are trying to become pregnant or if you could become pregnant and are not using effective contraception, as it may harm the unborn baby.

Pregnancy testing should be repeated regularly.

This medicine may slightly increase your chances of side effects from some contraceptive pills. If you have any side effects, talk to your doctor or pharmacist.

You should not breastfeed while you are taking this medicine. This is to avoid a risk of side effects for the baby since it may pass into breast milk.

Reporting 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.

Notes

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