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Velsipity (*etrasimod*)

An overview of Velsipity and why it is authorised in the EU

What is Velsipity and what is it used for?

Velsipity is a medicine used to treat people aged 16 years and over with ulcerative colitis (a disease causing inflammation and ulcers in the lining of the bowel). It is used to treat moderately to severely active disease when standard treatment or biological agents (medicines made by cells grown in a laboratory) have not worked well enough or cannot be used by the patient.

Velsipity contains the active substance etrasimod.

How is Velsipity used?

Velsipity can only be obtained with a prescription and should be started under the supervision of a doctor who has experience in managing ulcerative colitis.

The medicine is available as tablets to be taken once daily by mouth. When starting treatment with Velsipity, the medicine can temporarily cause a slower heart rate or problems with the heart rhythm, which may lead to dizziness or tiredness. To reduce the risk of such side effects, the medicine should be taken with food for the first 3 days of treatment.

For more information about using Velsipity, see the package leaflet or contact your doctor or pharmacist.

How does Velsipity work?

The active substance in Velsipity, etrasimod, blocks the action of a protein called sphingosine-1-phosphate (S1P) receptor, which is involved in controlling the movement of lymphocytes (a type of white blood cell involved in inflammation) in the body. By blocking the S1P receptor, etrasimod prevents lymphocytes from moving from the lymph nodes to the intestines. This is expected to help reduce inflammation in the bowel and other symptoms of the disease.

What benefits of Velsipity have been shown in studies?

Two main studies showed that Velsipity is more effective than placebo (a dummy treatment) at reducing inflammation and improving symptoms of moderate to severe ulcerative colitis. The studies

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involved a total of 743 people aged 16 years and over for whom standard treatment or other treatments did not work well enough or could not be used.

The main measure of effectiveness was clinical remission (a decrease in or disappearance of signs and symptoms of the disease), as measured using the modified Mayo score, a tool to assess disease activity in people with ulcerative colitis. Taken together, the results from the two studies showed that, after 12 weeks of treatment, 26% (129 out of 496) of those who received Velsipity had achieved clinical remission compared with 11% (27 out of 247) of those who received placebo.

One of these studies also looked at the longer-term effect of treatment and found that 32% (88 out of 274) of people taking Velsipity achieved clinical remission after 52 weeks compared with 7% (9 out of 135) for those receiving placebo.

Supportive data from the two studies also showed that, after 12 weeks, 19% (94 out of 496) of people treated with Velsipity had mucosal healing (no inflammation in the intestines based on endoscopy and assessment of an intestinal tissue sample), compared with 7% (16 out of 247) of those taking placebo. After 52 weeks of treatment, these figures were 27% (73 out of 274) and 8% (11 out of 135), respectively.

What are the risks associated with Velsipity?

For the full list of side effects and restrictions with Velsipity, see the package leaflet.

The most common side effects with Velsipity include lymphopenia (low levels of lymphocytes, which may affect more than 1 in 10 people) and headache (which may affect up to 1 in 10 people).

Velsipity must not be used in people who have a severely weakened immune system, those who have a severe active infection or long-term active infection such as hepatitis (inflammation of the liver) or tuberculosis and people with cancer or severe liver problems. It must also not be used in people who have, or have had, certain diseases affecting the heart rhythm, unless they have a functioning pacemaker. Additionally, Velsipity should not be used in those who have had certain diseases affecting the heart and blood vessels (such as heart attack) or problems with blood supply to the brain (such as stroke) in the last 6 months. The medicine should not be used by women who are pregnant or those who can become pregnant and are not using an effective form of contraception (birth control).

Why is Velsipity authorised in the EU?

Velsipity has been found to improve symptoms and inflammation in people with moderate to severe ulcerative colitis in the short and long term. Its side effects are generally mild to moderate and are comparable to those of other medicines that work in a similar way and are considered manageable with appropriate measures.

The European Medicines Agency decided that Velsipity's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Velsipity?

The company that markets Velsipity will provide educational materials for doctors and a guide for patients and their caregivers with important safety information about the medicine, its risks and its conditions for use. A patient card will also be given to women who can become pregnant with important information on the need to use effective contraception during treatment with Velsipity.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Velsipity have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Velsipity are continuously monitored. Suspected side effects reported with Velsipity are carefully evaluated and any necessary action taken to protect patients.

Other information about Velsipity

Velsipity received a marketing authorisation valid throughout the EU on 16 February 2024.

Further information on Velsipity can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/velsipity.

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