swissmedic

Summary report on authorisation dated 17 January 2025

Velsipity® (active substance: etrasimod)

Authorisation in Switzerland: 10 September 2024

Film-coated tablets for second-line treatment of adults with moderately to severely active ulcerative colitis (UC)

About the medicinal product

Velsipity contains the active substance etrasimod.

It is used to treat adults with moderately to severely active ulcerative colitis (UC) who have not responded adequately or are no longer responding to a conventional therapy or a biological agent[1] or who do not tolerate the therapy.

Ulcerative colitis is a chronic disease in which the intestinal mucosa, particularly in the rectum, repeatedly becomes inflamed and the inflammation spreads further through the colon. The disease usually occurs for the first time between the ages of 15 and 40 years. Typical symptoms include diarrhoea, often containing blood, frequent bowel movements with small amounts of stool, abdominal pain, a strong urge to defecate, and occasionally faecal incontinence. The inflammation usually begins gradually and gets worse over several weeks. Over the course of the disease, up to 25% of those affected develop symptoms outside of the bowel.

Velsipity was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least 2 of the 5 countries.
The authorisation application for Velsipity was submitted for assessment to the regulatory authorities in Singapore and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authority in its decision on the authorisation.

[1] Biological agent: medication manufactured using biotechnology.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Mode of action

Etrasimod, the active substance in Velsipity, is a sphingosine 1-phosphate (S1P) receptor modulator. Velsipity reduces the number of certain white blood cells (lymphocytes) in the blood. These white blood cells form part of the immune system and play a role in inflammation. When Velsipity is taken, the lymphocytes remain in the lymph nodes and do not move to the area of inflammation, which helps to reduce the inflammation in the colon. This reduction in inflammation helps to alleviate the symptoms and signs of ulcerative colitis.

Use

Velsipity is a prescription-only medicine.

It is available as a film-coated tablet in the dosage strength of 2 mg. The recommended dose is 2 mg once daily (1 film-coated tablet a day).

The film-coated tablets should be swallowed whole and can be taken with or without food.

The treatment with Velsipity should be supervised by a doctor with experience of treating ulcerative colitis.

Efficacy

The efficacy of Velsipity was investigated in two trials (ELEVATE UC 52 and ELEVATE UC 12) compared with a placebo (dummy drug).

Both trials involved patients aged between 16 and 80 with moderately to severely active ulcerative colitis (UC) who did not respond adequately or were no longer responding to one or more previous therapies or who did not tolerate these therapies.

In the ELEVATE UC 52 trial, 433 participants were treated over a period of 52 weeks. Alongside other evaluated parameters, 27% of the patients treated with etrasimod achieved clinical remission in week 12 [2] compared with 7% in the placebo group.

In the ELEVATE UC 12 trial, which involved 354 participants over 12 weeks, 25% of the patients treated with etrasimod achieved clinical remission compared with 15% in the placebo group.

[2] Clinical remission: Clinical remission means that patients with ulcerative colitis achieved a significant reduction in their disease symptoms. This includes normal stool frequency, no rectal bleeding, and normal endoscopic findings. Clinical remission is often used as the main indicator of successful treatment in trials.

Precautions, undesirable effects, & risks

Velsipity must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common short-term undesirable effect in more than 10% of all patients treated with Velsipity was lymphopenia (11%), a reduction in the number of lymphocytes (white blood cells) in the blood.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

There are currently very few treatment options for patients with moderately to severely active ulcerative colitis (UC) who do not respond adequately to the existing therapies or do not tolerate these therapies.

The trials conducted showed that Velsipity can achieve an improvement in disease symptoms and a reduction in bowel inflammation in a significant number of patients. In view of the high medical need of this patient group and the ability of Velsipity to achieve a significant improvement, the benefit-risk relationship was considered to be positive.

Swissmedic has therefore approved the medicinal product Velsipity, containing the active substance etrasimod, for use in Switzerland for the treatment of adults with moderately to severely active UC who have not responded adequately or are no longer responding to a conventional therapy or a biological agent, or who do not tolerate the therapy.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Velsipity®

Information for patients (package leaflet): Information for patients Velsipity®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.