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Omvoh® (active substance: mirikizumab)

First authorisation in Switzerland: 30 November 2023

Concentrate for solution for infusion for the treatment of adults with moderately to severely active ulcerative colitis

About the medicinal product

The medicinal product Omvoh contains the active substance mirikizumab and is used for the treatment of adult patients with moderately to severely active ulcerative colitis who have responded inadequately, or who no longer respond, to conventional therapies or a biological treatment. The medicinal product Omvoh is also indicated for patients for whom conventional therapies or a biological treatment are, or were, not suitable (due to contraindications[1] or intolerance.)

Ulcerative colitis (UC) is a chronic illness characterised by recurrent episodes of inflammation of the mucosa of the colon. UC can occur for the first time at any age, but most frequently first appears between the ages of 15 and 30 and, to a lesser extent, between the ages of 50 and 70. UC affects both sexes equally.

Mode of action

Omvoh, containing the active substance mirikizumab, is a humanised monoclonal antibody (an immunologically active protein). This antibody was specifically developed to bind to a protein named interleukin-23, which plays an important role in inflammatory processes in the body. By binding to interleukin-23, mirikizumab prevents this protein from performing its function, causing the inflammatory process, including in the colonic mucosa, to be suppressed. As a result, Omvoh can help alleviate the symptoms of UC and prevent complications.

[1] Contraindicated: A contraindication is a circumstance or criterion (e.g. pregnancy) that prohibits the use of a medicine or therapeutic procedure for the envisaged indication

Administration

Omvoh is a prescription-only medicine.

At the recommended dosage of Omvoh, a distinction is made between two phases: the start (induction) of treatment and maintenance therapy:

1. An induction dose of Omvoh is administered to start the treatment. This dose of 300 mg is administered as an intravenous infusion (into the veins) over at least 30 minutes in weeks 0, 4 and 8.
2. During maintenance therapy, Omvoh is administered subcutaneously (under the skin) as a solution for injection containing 100 mg of Omvoh in a pre-filled syringe. The dose is 200 mg (i.e. two pre-filled syringes or 2 pre-filled pens) in the 12th week and then every 4 weeks.

The dosage can be adjusted depending on the disease activity and the patient's tolerance.

Efficacy

The efficacy of Omvoh has been investigated in two studies (LUCENT-1 and LUCENT-2) involving adult patients with moderately to severely active ulcerative colitis.

The trial participants had a confirmed diagnosis of ulcerative colitis for at least three months and a modified Mayo score[2] of 4 to 9 (out of a possible 9 points), which equates to moderate or severe disease activity. The patients had also responded inadequately to, or were unable to tolerate, conventional therapies or a biological treatment.

In the LUCENT-1 trial, the patients received either an induction dose of 300 mg Omvoh or a placebo (dummy drug) in the form of an intravenous infusion in week 0, week 4 and week 8. The primary efficacy endpoint[3] for the induction study was the number of patients in clinical remission (defined as a clinical improvement based on the Mayo score) in the 12th week.

In the LUCENT-2 trial, patients who had shown a clinical response in the 12th week of the LUCENT-1 trial were reassigned to a treatment group and received either a subcutaneous maintenance dose of 200 mg Omvoh or a placebo every four weeks for 40 weeks.

The study results showed that a significantly greater proportion of patients treated with Omvoh achieved clinical remission compared to the placebo group, both in the 12th week (24.2% versus 13.3%) and the 40th week (49.9% versus 25.1%). This indicates that the medicinal product Omvoh is an effective treatment for moderately to severely active ulcerative colitis.

[2] Mayo score: The Mayo score is used to evaluate the disease activity in ulcerative colitis and is based on various criteria, including stool frequency, rectal bleeding, an endoscopic finding and the doctor's global assessment. The doctor's global assessment was disregarded in these studies, hence the use of a "modified Mayo score".

[3] Primary efficacy endpoint: The primary endpoint is the main objective of the trial determined before the start of the study. If the primary endpoint is reached or exceeded, the trial proves that a treatment is effective. Secondary endpoints, on the other hand, refer to effects that do not clearly prove efficacy or that do not allow any clear conclusions to be drawn about the actual target criterion (primary endpoint).

Precautions, undesirable effects, & risks

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

Common undesirable effects of Omvoh include headaches, upper respiratory tract infections, pains in the joints and injection site reactions.

As a precaution, patients receiving Omvoh should seek medical advice if they notice signs or symptoms of an infection. If a serious infection occurs, patients should be closely monitored and the administration of Omvoh discontinued until the infection has resolved. Before treatment starts, patients should also be evaluated for tuberculosis infection. Omvoh should not be administered in the event of active tuberculosis. Particular caution is indicated if Omvoh is administered to patients suffering from chronic or recurrent infections. The overall risk of infection is also increased during the administration of Omvoh.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The completed studies show that Omvoh can significantly alleviate symptoms in patients with moderately to severely active ulcerative colitis who have responded inadequately to, or were unable to tolerate, conventional therapies or biological treatments. For these patients, Omvoh meets an important medical need.

Taking all the risks and precautions into account, and based on the available data, the benefits of Omvoh outweigh the risks.

Swissmedic has therefore authorised the medicinal product Omvoh, containing the active substance mirikizumab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Omvoh®

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 Public Summary SwissPAR.

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