



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/590451/2024
EMA/H/C/005122

OmvoH (*mirikizumab*)

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

What is OmvoH and what is it used for?

OmvoH is a medicine used to treat adults with:

- ulcerative colitis, a disease that causes inflammation of the large intestine, leading to ulceration and bleeding.
- Crohn's disease, an inflammatory disease affecting the gut.

OmvoH is used to treat moderately to severely active ulcerative colitis and Crohn's disease when conventional therapy or biological treatments have not worked well enough, have stopped working, or have caused unacceptable side effects.

OmvoH contains the active substance mirikizumab.

How is OmvoH used?

OmvoH can only be obtained with a prescription and should be used under the supervision of a doctor experienced in diagnosing and treating ulcerative colitis or Crohn's disease.

OmvoH is given as an infusion (drip) into a vein and as an injection under the skin using a pre-filled pen or syringe. Treatment starts with an infusion into a vein lasting at least 30 minutes for patients with ulcerative colitis or at least 90 minutes for patients with Crohn's disease, given 3 times over 8 weeks. For patients with ulcerative colitis, another 3 infusions may be given every 4 weeks if the doctor considers that OmvoH is not working well enough.

Once the patient has completed treatment with infusions, they begin long-term maintenance treatment which is given as two separate injections under the skin, 4 weeks after the last infusion and every 4 weeks thereafter.

After being trained, patients may inject OmvoH themselves if the doctor or nurse considers it appropriate. For more information about using OmvoH, see the package leaflet or contact your doctor or pharmacist.



How does Omvoh work?

The active substance in Omvoh, mirikizumab, is an antibody (a type of protein) designed to attach to interleukin-23 (IL-23) and block its activity. IL-23 is a protein that controls the growth and maturation of some types of T cells. These T cells, which are part of the immune system (the body's natural defences), are involved in causing inflammation that is linked to ulcerative colitis and Crohn's disease. By blocking the action of IL-23, Omvoh reduces inflammation and symptoms associated with these diseases.

What benefits of Omvoh have been shown in studies?

Ulcerative colitis

Two main studies looked at how effective Omvoh was at treating patients with moderately to severely active ulcerative colitis, for whom other treatments did not work well enough or caused unacceptable side effects.

In the first study involving 1,162 patients, 24% (210 out of 868) of those who received the recommended dose of Omvoh infusions over 8 weeks had clinical remission (a decrease in or disappearance of signs and symptoms of the disease) after 12 weeks compared with 13% (39 out of 294) of patients who received placebo (a dummy treatment). Clinical remission was evaluated by the modified Mayo score (MMS), which measures changes in stool frequency, rectal (last several inches of the large intestine closest to the anus) bleeding and endoscopic subscore (measure of inflammation in the intestines based on a procedure that uses a tube with a camera to look inside the body).

A second study involving 544 patients from the first main study who responded to Omvoh looked at the effectiveness of maintenance treatment at a lower dose given every 4 weeks by injection under the skin. After 40 weeks, around 50% (182 out of 365) of patients receiving Omvoh were in clinical remission, as evaluated by the MMS score, compared with 25% (45 out of 179) who received placebo.

Crohn's disease

A main study in 1,152 patients looked at how effective Omvoh was in treating moderately to severely active Crohn's disease when other treatments did not work well enough or caused unacceptable side effects.

In this study, 38% of patients who received Omvoh (220 out of 579) had improvements in bowel symptoms after 12 weeks and improvements in bowel inflammation after 52 weeks compared with 9% of those who received placebo (18 out of 199). In addition, about 45% of patients receiving Omvoh (263 out of 579) had improvements in bowel symptoms after 12 weeks and substantial reductions in the overall severity of their disease after 52 weeks, compared with about 20% of patients who received placebo (39 out of 199).

What are the risks associated with Omvoh?

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

The most common side effects with Omvoh (which may affect more than 1 in 10 people) are reactions at the site of injection (when given by injection under the skin). Other common side effects with Omvoh (which may affect up to 1 in 10 people) include upper respiratory tract infections (nose and throat infections), arthralgia (joint pain), headache, and rash.

Omvoh must not be used in patients with active serious infections such as tuberculosis.

Why is Omvoh authorised in the EU?

Omvoh has been shown to provide benefits in adults with moderately to severely active ulcerative colitis and Crohn's disease for whom conventional or biological treatments did not work or are not tolerated. In around half of patients with ulcerative colitis who responded to treatment, the positive effects were maintained with continued use. The side effects of Omvoh are considered manageable, with the most important side effect being infection. Information regarding long-term use of Omvoh is limited and studies are ongoing to evaluate this.

The European Medicines Agency therefore decided that Omvoh'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 Omvoh?

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

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

Other information about Omvoh

Omvoh received a marketing authorisation valid throughout the EU on 26 May 2023.

Further information on Omvoh can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/omvoh.

This overview was last updated in 01-2025.