Package leaflet: Information for the patient

Omvoh® 300 mg concentrate for solution for infusion
mirikizumab

▼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 the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Omvoh is and what it is used for

Omvoh contains the active substance mirikizumab, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain target proteins in the body. Omvoh works by attaching to and blocking a protein in the body called IL-23 (interleukin-23), which is involved in inflammation. By blocking the action of IL-23, Omvoh reduces inflammation and other symptoms associated with ulcerative colitis.

Ulcerative colitis is a chronic inflammatory disease of the large bowel. If you have ulcerative colitis, you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Omvoh to reduce signs and symptoms of ulcerative colitis such as diarrhoea, abdominal pain, urgency and rectal bleeding.

2. What you need to know before you receive Omvoh

Do not use Omvoh
- if you are allergic to mirikizumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Omvoh.
- If you have important active infections (active tuberculosis).

Warnings and precautions

- Talk to your doctor or pharmacist before using this medicine.
- Your doctor will check how well you are before treatment.
- Make sure you tell your doctor about any illness you have before treatment.

Infections

- Omvoh can potentially cause serious infections.
- Treatment with Omvoh should not be started if you have an active infection until the infection is gone.
- After starting the treatment, tell your doctor right away if you have any symptoms of an infection such as:
    - fever
    - chills
    - muscle aches
    - cough
    - shortness of breath
    - runny nose
    - sore throat
    - pain during urination

- Also tell your doctor if you have recently been near anyone who might have tuberculosis.
- Your doctor will examine you and may do a test for tuberculosis before you have Omvoh.
- If your doctor thinks you are at risk of an active tuberculosis, you may be given medicines to treat it.

Vaccinations

Your doctor will check to see if you need any vaccinations before starting treatment. Tell your doctor, pharmacist or nurse if you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Omvoh.

Allergic reactions

- Omvoh can potentially cause serious allergic reactions.
- Stop using Omvoh and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
    - rash
    - fainting
    - dizziness
    - low blood pressure
    - swelling of the face, lips, mouth, tongue or throat, trouble breathing
    - sensation of throat tightening or chest tightness.

Liver blood test

Your doctor will conduct blood tests before starting and during treatment with Omvoh to check if your liver is functioning normally. If blood tests are abnormal, your doctor might interrupt therapy with Omvoh and do additional tests on your liver to determine the cause.

Children and adolescents

Omvoh is not recommended for children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Omvoh

Tell your doctor, pharmacist or nurse

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Omvoh.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this medicine. It is preferable to avoid the use of Omvoh in pregnancy. The effects of Omvoh in pregnant women are not known. If you are a woman of childbearing potential,

you are advised to avoid becoming pregnant and should use effective contraception while using Omvoh and for at least 10 weeks after the last Omvoh dose.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine.

Driving and using machines
Omvoh is unlikely to influence your ability to drive and use machines.

Omvoh contains sodium
This medicine contains 60 mg sodium (main component of cooking/table salt) in each 300 mg dose. This is equivalent to 3 % of the recommended maximum daily dietary intake of sodium for an adult. Before Omvoh is given to you, it is mixed with a solution that might contain sodium. Talk to your doctor if you are on a low salt diet.

3. How Omvoh is used

Omvoh is intended for use under the guidance and supervision of a doctor experienced in the diagnosis and treatment of ulcerative colitis.

How much Omvoh is given and for how long
Your doctor will decide how much Omvoh you need and for how long. Omvoh is for long-term treatment. Your doctor or nurse will regularly monitor your condition to check that the treatment is having the desired effect.

- Treatment start: The first dose of Omvoh is 300 mg and will be given by your doctor by intravenous infusion (drip in a vein in your arm) over at least 30 minutes. After the first dose, you will receive another dose of Omvoh 300 mg 4 weeks later and again after an additional 4 weeks.
  If you do not have adequate therapeutic response after these 3 infusions, your doctor might consider continuing intravenous infusions at weeks 12, 16 and 20.

- Maintenance therapy: 4 weeks after the last intravenous infusion, a maintenance dose of Omvoh 200 mg will be given by an injection under the skin (‘subcutaneously’) and then every 4 weeks. The maintenance dose of 200 mg will be given by using 2 injections each containing 100 mg of Omvoh.
  If you lose response after receiving the maintenance dose of Omvoh, your doctor may decide to give you 3 doses of Omvoh by intravenous infusions.
  Your doctor or nurse will tell you when to switch to subcutaneous injections.
  During maintenance therapy you and your doctor or nurse should decide if you should inject Omvoh yourself after training in subcutaneous injection technique. It is important not to try to inject yourself until you have been trained by your doctor or nurse. Your doctor or nurse will offer the necessary training.

If you receive more Omvoh than you should
If you have received more Omvoh than you should or the dose has been given sooner than prescribed, inform your doctor.

If you forget to use Omvoh
If you missed a dose of Omvoh, talk to your doctor.

If you stop using Omvoh
You should not stop using Omvoh without speaking to your doctor first. If you stop treatment, symptoms of ulcerative colitis may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)
- Upper respiratory tract infections (nose and throat infections)
- Joint pain
- Headache
- Rash
- Injection site reactions (e.g. red skin, pain)

Uncommon (may affect up to 1 in 100 people)
- Shingles
- Infusion-related allergic reaction (e.g. itch, hives)
- Increase in the level of liver enzymes in your blood

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 this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: 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.

5. How to store Omvoh

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label and on the outer carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C - 8 °C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Do not use this medicine if you notice that the vial is damaged, or the medicine is cloudy, distinctly brown, or has particles in it.

This medicine is for single use only.

Do not throw away any medicines via wastewater. Ask your doctor, nurse or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Diluted solution
It is recommended to start the infusion immediately after dilution. If not immediately used, the diluted solution prepared with sodium chloride 9 mg/mL (0.9 %) solution for injection may be stored refrigerated (2 ºC – 8 ºC) for not more than 96 hours or at room temperature not exceeding 25 ºC for not more than 10 hours (total time must not exceed 96 hours) starting from the time of vial puncture. The diluted infusion solution prepared with 5 % glucose must be used within 48 hours, of which not more than 5 hours are permitted at nonrefrigerated temperature not to exceed 25 °C, starting at the time of vial puncture.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and

would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Keep the diluted solution away from direct heat or light.
Do not freeze the diluted solution.

6. Contents of the pack and other information

What Omvoh contains
- The active substance is mirikizumab.
  Each vial contains 300 mg mirikizumab in 15 mL (20 mg/mL).
- The other ingredients are sodium citrate dihydrate; citric acid, anhydrous; sodium chloride; polysorbate 80; water for injections.

What Omvoh looks like and contents of the pack
Omvoh is a solution in a clear glass vial. Its colour may vary from colourless to slightly yellow.

Pack size of 1 vial.

Marketing Authorisation Holder
Eli Lilly Nederland B.V.
Papendorpseweg 83
3528 BJ Utrecht
The Netherlands

Manufacturer
Lilly France S.A.S.
Rue du Colonel Lilly
67640 Fegersheim
France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom (Great Britain)
Eli Lilly and Company Limited
Tel: + 44-(0) 1256 315000

This leaflet was last revised in June 2023

OM005

----------✂----------

Omvoh 300 mg concentrate for solution for infusion
mirikizumab

The following information is intended for healthcare professionals only:

Do not use Omvoh that has been frozen.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Dilution prior to intravenous infusion

1. Each vial is for single use only.
2. Prepare the infusion solution using aseptic technique to ensure the sterility of the prepared solution.
3. Inspect the content of the vial. The concentrate should be clear, colourless to slightly yellow and free of visible particles. Otherwise, it should be discarded.
4. Withdraw 15 mL of the mirikizumab vial (300 mg) using an appropriately sized needle (18 to 21 gauge is recommended) and transfer to the infusion bag. The concentrate should be diluted only in infusion bags (bag size ranging from 50-250 mL) containing either sodium chloride 9 mg/mL (0.9 %) solution for injection or 5% glucose solution for injection. The final concentration after dilution is approximately 1.2 mg/mL to approximately 6 mg/mL.
5. Gently invert the infusion bag to mix. Do not shake the prepared bag.

Administration of the diluted solution

6. The intravenous administration set (infusion line) should be connected to the prepared intravenous bag and the line should be primed. The infusion should be administered for at least 30 minutes.
7. At the end of the infusion, to ensure a full dose is administered, the infusion line should be flushed with sodium chloride 9 mg/mL (0.9 %) solution or 5 % glucose solution for injection. The flush should be administered at the same rate as used for Omvoh administration. The time required to flush Omvoh solution from the infusion line is in addition to the minimum 30 minutes infusion time.