Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a physician's prescription only

Omvoh 300 mg

Concentrate in vial for solution for infusion

The active ingredient and its concentration:
Each vial contains 300 mg mirikizumab in 15 ml solution (20 mg/mL).
Inactive ingredients and allergens in the preparation: see chapter 2 section "Important information about some of the ingredients of this medicine" and Chapter 6 "Additional Information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information regarding this medicine. If you have any further questions, contact your doctor or pharmacist.
This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Omvoh is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic treatment.

Omvoh contains the active substance mirikizumab, a monoclonal antibody. Monoclonal antibodies are proteins that recognize 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 diarrhea, abdominal pain, urgency and rectal bleeding.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are hypersensitive (allergic) to the active ingredient (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.
- you have important active infections (active tuberculosis).

Special warnings regarding the use of this medicine

- 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 intended for children and adolescents under 18 years of age because it has not been studied in this age group.

Drug interactions
If you are taking or have recently taken any other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist.
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. The doctor will decide with you whether to stop breastfeeding or to stop/avoid Omvoh treatment, considering the benefit of breastfeeding for the child and the benefit of treatment for the woman.

Driving and using machines
Omvoh has no or negligible effect on your ability to drive and use machines.

Important information about some of the ingredients of this medicine

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, so in practice the amount of sodium may be higher. Talk to your doctor if you are on a low salt diet.

3. HOW TO USE THIS MEDICINE?

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

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine. The dosage and manner of treatment will be determined only by your doctor.

The acceptable dose of Omvoh and for how long given
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.

Do not exceed the recommended dose.

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.

Persist with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

Like all medicines, Omvoh can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them.

Common side effects (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 side effects (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.

If a side effect has appeared, if one of the side effects worsens or if you suffer from a side effect not specified in the leaflet, you must consult the doctor.

Reporting Side Effects
Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects due to Drug Treatment” that can be found on the Home Page of the Ministry of Health’s website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

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

Storage conditions:
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 or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Diluted solution
The medical staff will prepare the readymade preparation for intravenous administration. 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 (2ºC – 8ºC) for not more than 96 hours or at room temperature not exceeding 25ºC 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 and kept refrigerated, must be used within 48 hours, of which not more than 5 hours are permitted at nonrefrigerated temperature not to exceed 25°C. The total time must not exceed 48 hours, 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. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:
Sodium chloride, sodium citrate dihydrate, polysorbate 80, citric acid anhydrous, water for Injection.

What the medicine looks like and contents of the pack:
Omvoh is a solution in a clear glass vial. The solution is clear to opalescent, colorless to slightly yellow to slightly brown and it is free of particles.
Pack size of 1 vial.

Registration holder's name and address: Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana 4366411.

Manufacturer's name and address: Eli Lilly & Company, Indianapolis, Indiana, USA.

Approved in January 2024 according to MOHs guidelines.

Drug registration number at the national medicine's registry of the Ministry of Health:
174-96-37707-00

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