

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

This medicine is dispensed with a physician's prescription only

**OmvoH 100 mg
solution for injection in a pre-filled pen**

The active ingredient and its concentration:

Each pre-filled pen contains 100 mg of mirikizumab in 1 ml solution.

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 less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium -free".

3. HOW TO USE THIS MEDICINE?

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 start of treatment with Omvoh will be done under the guidance and supervision of a doctor experienced in the diagnosis and treatment of ulcerative colitis.

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.

A caregiver may also give you your Omvoh injection after proper training.

Use a reminder method such as notes in a calendar or diary to help you remember when to take your next dose so that you avoid missing or repeating doses.

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 have forgotten to inject a dose of Omvoh, inject as soon as possible. Thereafter, resume dosing every 4 weeks.

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 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.

Do not microwave the pens, **do not** run hot water over them, and **do not** leave them in direct sunlight.

Do not shake your pre-filled pen.

Store in the original packaging in order to protect from light.
Omvoh may be stored unrefrigerated for up to 2 weeks at a temperature not above 30°C.
If these conditions are exceeded, Omvoh must be discarded.

Do not use this medicine if you notice that the pre-filled pen is damaged, or if 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.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Sodium Chloride; sodium citrate dihydrate; citric acid, anhydrous; polysorbate 80; water for injection.

What the medicine looks like and contents of the pack:

Omvoh is a solution in a clear glass cartridge encased in a disposable, single-use pen. The solution is clear to opalescent, colorless to slightly yellow to slightly brown and it is free of particles.

Pack size of 2 pre-filled pens.

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:
174-95-37706-00

Instructions for use
OmvoH 100 mg solution for injection in a pre-filled pen
mirikizumab

2 pre-filled pens



Read this before you inject OmvoH. Follow all the step-by-step instructions.

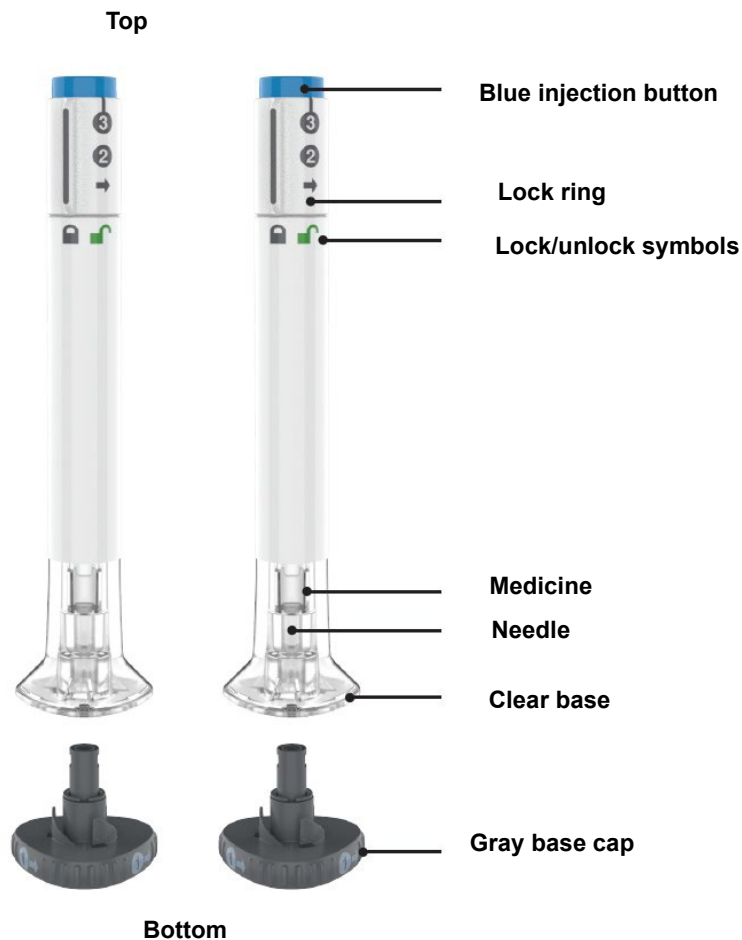
- **2 OmvoH injections are required for a full dose.**
- Inject 1 OmvoH pen followed right away by the other OmvoH pen.

Also keep in mind:

- Your healthcare provider should show you how to prepare and inject OmvoH using the pen. **Do not** inject yourself or someone else until you have been shown how to inject OmvoH.
- Each OmvoH pen is for one-time use only. Do not share or reuse your pen. You may give or get an infection.
- Your healthcare provider may help you decide where on your body to inject your dose. You can also read the “Choose your injection site” section of these instructions to help you choose which area can work best for you.
- If you have vision or hearing problems, do not use OmvoH pen without help from a caregiver.
- Keep the Instructions for use and refer to them as needed.

Before you use the Omvoh pens, read and carefully follow all the step-by-step instructions.

Parts of the Omvoh pen



100 mg/mL + 100 mg/mL = 1 Full dose

IMPORTANT:

- 2 injections are required for a full dose.
- Inject 1 pen followed right away by the other pen.

Preparing to inject Omvoh

Take the pens from the refrigerator

Take 2 Omvoh pens from the refrigerator.

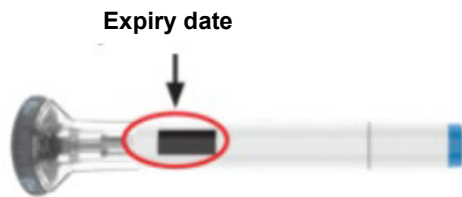
Leave the gray base caps on until you are ready to inject.

Leave the pens at room temperature for 30 minutes before injecting.

Do not microwave the pens, **do not** run hot water over them, and **do not** leave them in direct sunlight.

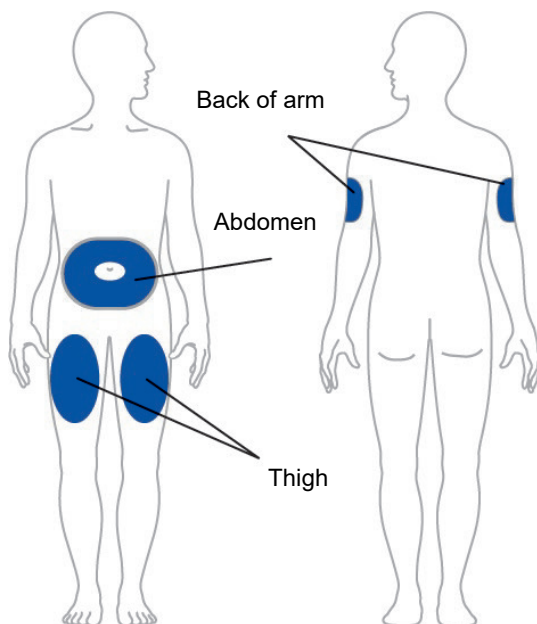
Gather supplies

Inspect the pens and the medicine



Prepare for injection

Choose your injection site



Injecting Omvoh

Do not use the pens if the medicine is frozen.
Do not shake.

Supplies:

- 2 alcohol wipes
- 2 cotton balls or pieces of gauze
- 1 sharps container (see “Disposing of Omvoh pens”)

Make sure you have the right medicine. The medicine inside should be clear. It may be colorless to slightly yellow.

Do not use the pens, and dispose of as directed by your healthcare provider if:

- it looks damaged
- the medicine is cloudy, is discolored, or has particles
- the expiry date printed on the label has passed
- the medicine is frozen

Wash your hands with soap and water before you inject Omvoh.

Your healthcare provider can help you choose the injection site that is best for you.

- **You or another person** may inject the medicine into your stomach area (abdomen). **Do not** inject within 5 centimeters of the belly button (navel).
- **You or another person** may inject the medicine in the front of your thighs. This area should be at least 5 centimeters above the knee and 5 centimeters below the groin.
- **Another person** may give you the injection in the back of your upper arm.
- **Do not** inject in the exact same spot every time. For example, if your first injection was in your abdomen, your second injection - to complete a full dose - could be in another spot in your abdomen.
- **Do not** inject into areas where the skin is tender, bruised, red or hard.

Clean the injection site with an alcohol wipe. Let the injection site dry before you inject your medicine.

1 Uncap the pen

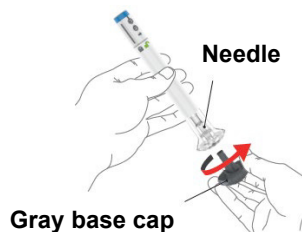


Make sure the pen is locked.



Leave the gray base cap on until you are ready to inject.

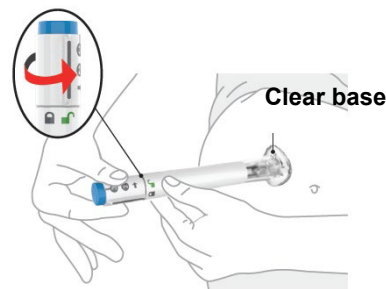
- Twist off the gray base cap and throw it away in your household waste.
- **Do not** put the gray base cap back on – this could damage the needle.
- **Do not** touch the needle.



2 Place and Unlock

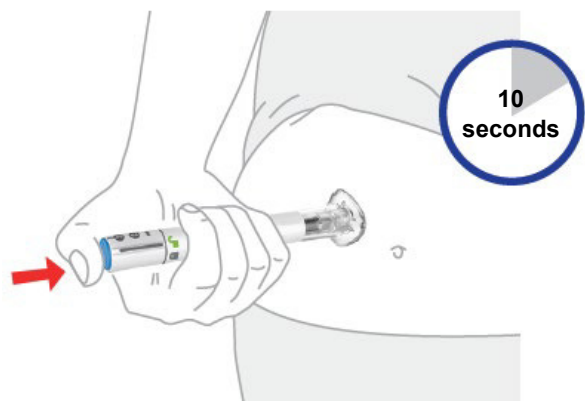
- Place and hold the clear base flat and firmly against your skin.

Keep the base on your skin and turn the lock ring to the **unlock** position.



3 Press and Hold for up to 10 Seconds

- Press and hold the blue injection button. You will hear a loud click (injection started).
- **Keep holding the clear base firmly against your skin.** You will hear a second loud click in about 10 seconds after the first one (injection completed).



- You will know the injection is complete when the gray plunger is visible.
- Remove the pen from your skin.
- If you have bleeding at the injection site, press a cotton ball or gauze over the injection site.
- **Do not** rub the injection site.

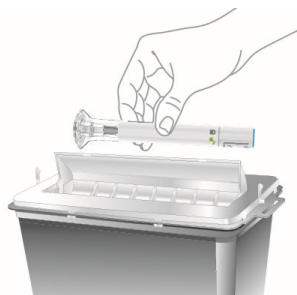


2 injections are required for a full dose. Inject one pen immediately followed by the other pen.

Disposing of Omvoh pens

Throw away the used pens

- Put the used pen in a sharps disposal container right away after use. Do not throw the pen directly into your household waste.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant,
 - properly labelled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how you should throw away needles and syringes.
- Do not recycle your used sharps disposal container.
- For more information on how to dispose of the container properly, ask your healthcare provider about options available in your area.



Commonly asked questions

Q. What if I let my pens warm up for longer than 30 minutes before injecting?

A. Your pen can stay at room temperature up to 30°C for up to 2 weeks.

Q. What if I see air bubbles in the pen?

A. It is normal to have air bubbles in the pen. They will not harm you or affect your dose.

Q. What if there is a drop of liquid on the tip of the needle when I remove the gray base cap?

A. It is okay to see a drop of liquid on the tip of the needle. This will not harm you or affect your dose.

Q. What if I unlocked the pen and pressed the blue injection button down until the injection is complete?

A. **Do not** remove the gray base cap. Do not use the pen. Talk to your doctor or pharmacist to get a new one.

Q. Do I need to hold the blue injection button down until the injection is complete?

A. You do not need to hold the blue injection button down, but it may help you keep the pen steady and firm against your skin.

Q. What if the needle did not retract after my injection?

A. **Do not** touch the needle and **do not** replace the gray base cap. Store the pen in a safe place to avoid an accidental needlestick and contact your doctor, pharmacist or nurse.

Q. What if there is a drop of liquid or blood on my skin after my injection?

A. This is normal. Press a cotton ball or gauze over the injection site. **Do not** rub the injection site.

Q. What if I heard more than 2 clicks during my injection – 2 loud clicks and a soft one. Did I get my complete injection?

A. Some patients may hear a soft click right before the second loud click. That is the normal operation of the pen. **Do not** remove the pen from your skin until you hear the second loud click.

Q. How can I tell if my injection is complete?

A. After you press the blue injection button, you will hear 2 loud clicks. The second loud click tells you that your injection is complete. You will also see the gray plunger at the top of the clear base.

Read the full package leaflet for Omvoh inside this box to learn more about your medicine.