Instructions for use

Omvoh® 100 mg solution for injection in pre-filled pen

mirikizumab

2 pre-filled pens: 1 pen 100 mg and 1 pen 100 mg



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

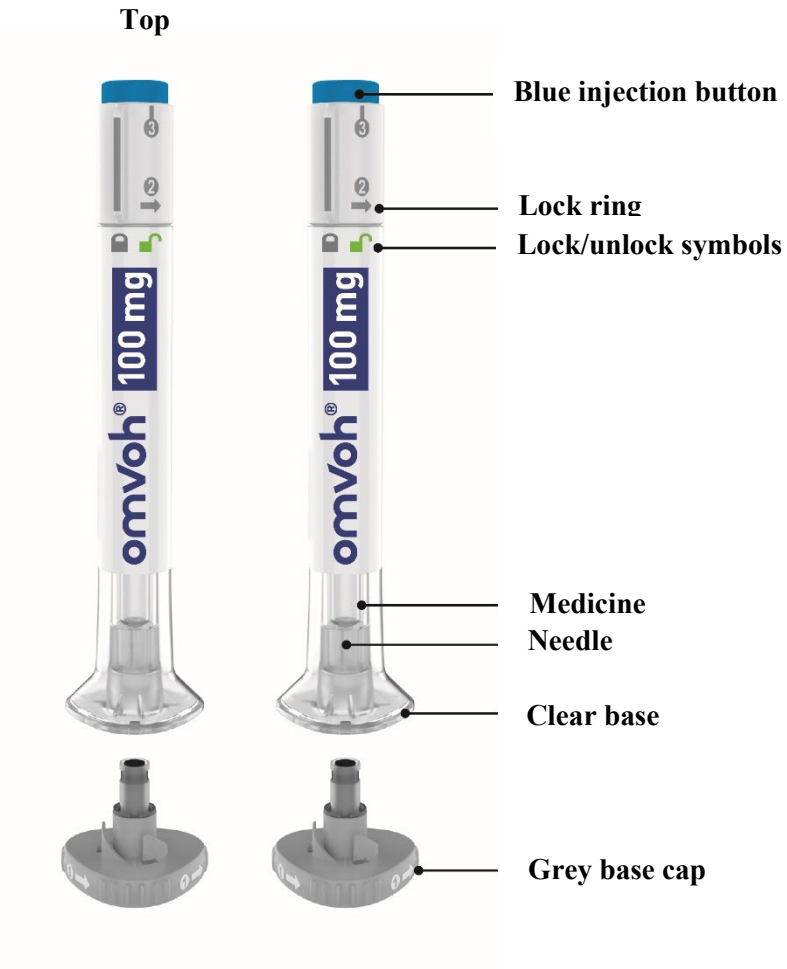
- **2 Omvoh injections are required for a full dose to treat ulcerative colitis.**
- Inject 1 Omvoh pen followed right away by the other Omvoh pen.

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 + 100 mg = 1 Full dose

IMPORTANT:

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

Preparing to inject Omvoh

Take the pens from the refrigerator

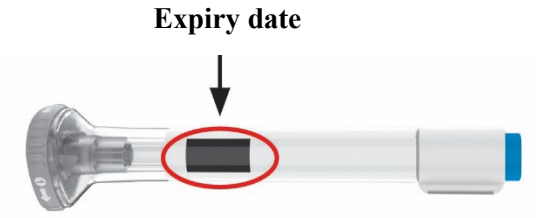
Take 2 Omvoh pens from the refrigerator.
Leave the grey base caps on until you are ready to inject.
Leave the pens at room temperature for 30 minutes before injecting.
Do not microwave the pens, run hot water over them, or leave them in direct sunlight.
Do not use the pens if the medicine is frozen.
Do not shake.

Gather supplies

Supplies:
• 2 alcohol wipes
• 2 cotton balls or pieces of gauze
• 1 sharps container (see "Disposing of Omvoh pens")

Inspect the pens and the medicine

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



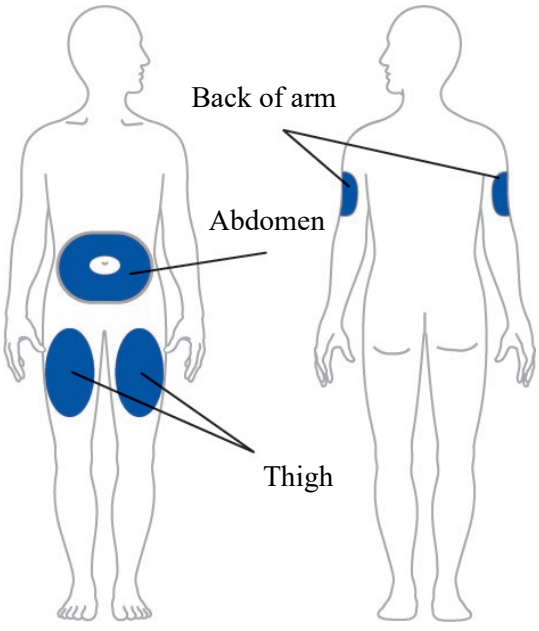
Do not use the pens, and dispose of as directed by your healthcare provider if:
• it looks damaged
• the medicine is cloudy, is discoloured, or has particles
• the expiry date printed on the label has passed
• the medicine is frozen

Prepare for injection

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

Choose your injection site

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



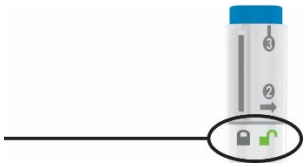
- **You or another person** may inject the medicine into your stomach area (abdomen). **Do not** inject within 5 centimetres of the belly button (navel).
- **You or another person** may inject the medicine in the front of your thighs. This area should be at least 5 centimetres above the knee and 5 centimetres 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.

Injecting Omvoh

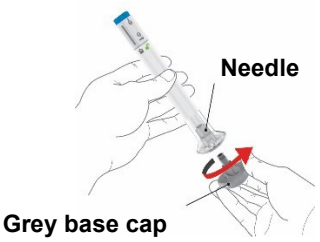
1 **Uncap the pen**

Make sure the pen is locked.



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

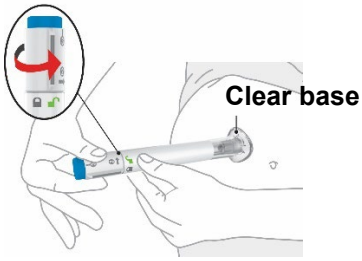
- Twist off the grey base cap and throw it away in your household waste.
- **Do not** put the grey base cap back on – this could damage the needle.
- **Do not** touch the needle.



2 **Place and Unlock**

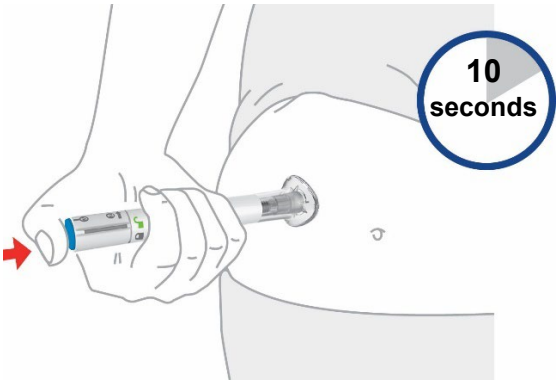
- Place and hold the clear base flat and firmly against your skin.

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

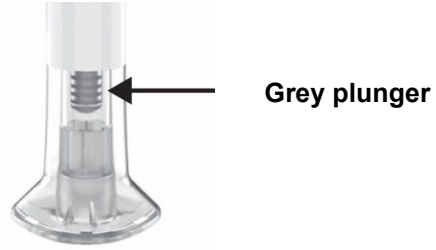


3 **Press and Hold for up to 10 Seconds**

- 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 grey 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.

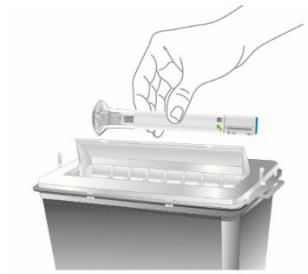


2 injections are required for a full dose. Inject one pen immediately followed by the other pen.

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 pens.

- 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 grey 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 grey 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 or replace the grey 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 grey plunger at the top of the clear base.

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

Last revised in August 2025.

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