

**INSTRUCTIONS FOR USE
OMVOH™ (ahm-VOH)**

(mirikizumab-mrkz)

**injection, for subcutaneous use
100 mg/mL prefilled pen**

This Instructions for Use contains information on how to inject OMVOH.



Before you use the OMVOH prefilled pens (Pens), read and carefully follow all the step-by-step instructions. Two injections are required for a full dose.

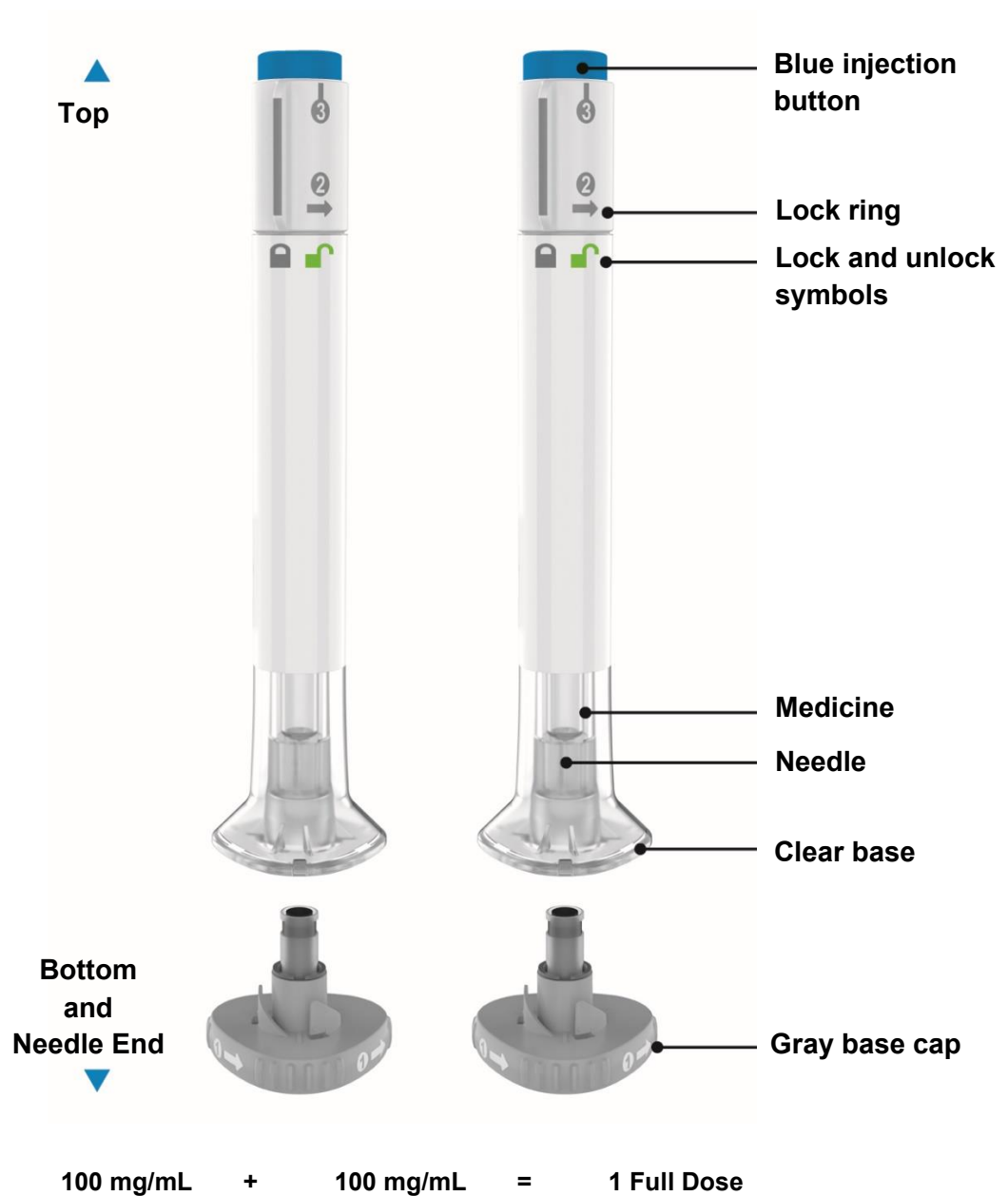
Important information you need to know before injecting OMVOH:

- **For injections under the skin (subcutaneous injection) only.**
- 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.
- Keep this Instructions for Use and read it as needed.
- **2 OMVOH injections are required for a full dose.**
- **Inject 1 OMVOH Pen followed right away by the other OMVOH Pen.**
- Each OMVOH Pen is for **1-time use only**.
- The OMVOH Pen contains glass parts. Handle it carefully. If you drop it on a hard surface do not use it. Use a new OMVOH Pen for your injection.
- 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.
- See **Storing OMVOH Pens** for important storage information.

INSTRUCTIONS FOR USE

Before you use the OMVOH Pens, read and carefully follow all the step-by-step instructions.

Parts of the OMVOH Pen



Important:

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

2 injections are required for a full dose. Inject one Pen immediately followed 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, or run hot water over them, or leave them in direct sunlight.

Do not shake the Pens.

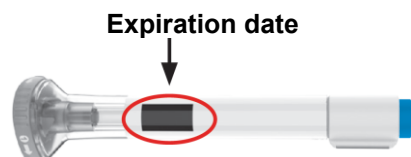
Gather supplies

Supplies:

- 2 alcohol wipes
- 2 cotton balls or pieces of gauze
- 1 sharps container (see **Throwing away (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 colorless to slightly yellow to slightly brown.



Do not use the Pens and throw away (dispose of) as directed by your healthcare provider or pharmacist if:

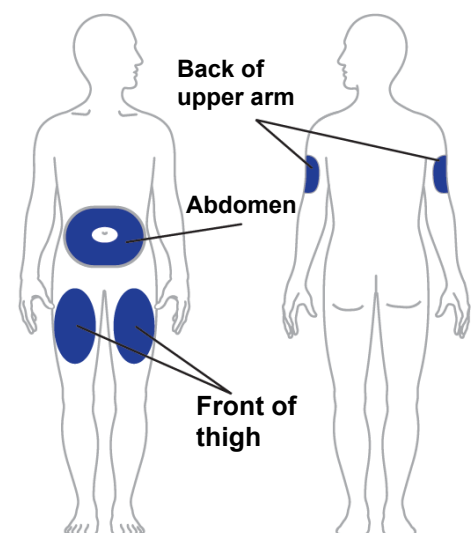
- one or both Pens look damaged
- the medicine is cloudy, is discolored, or has particles
- the expiration date printed on the label has passed
- the medicine is frozen

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 2 inches 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 2 inches above the knee and 2 inches 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) should be in another spot in your abdomen, or upper arm, or thigh.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard.

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

Injecting OMVOH

1 Uncap the Pen

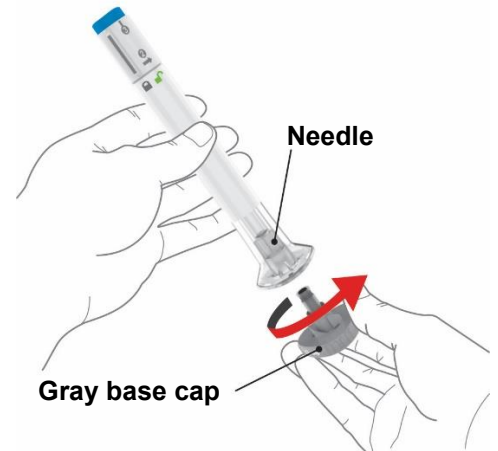


Make sure the Pen is **locked**.



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 trash.
- **Do not** put the gray base cap back on. This could damage the needle.
- **Do not** touch the needle.

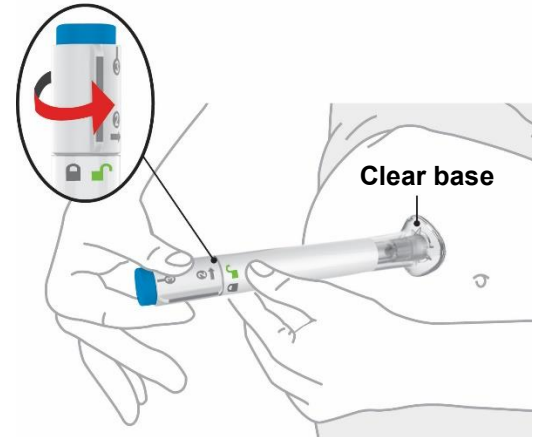


2 Place and unlock

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

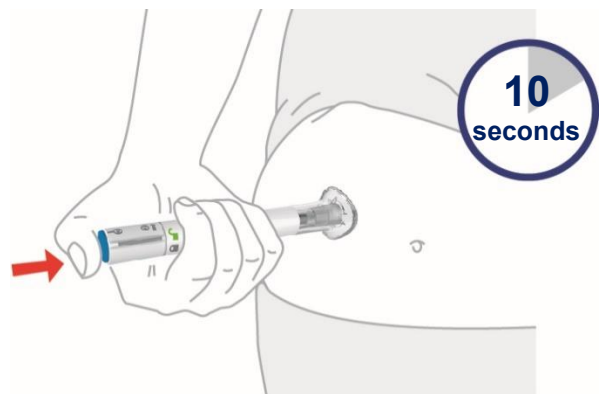


Keep the clear base on the skin, then turn the lock ring to the **unlock** position.



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 the 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 the 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, as this may cause bruising.



Gray plunger

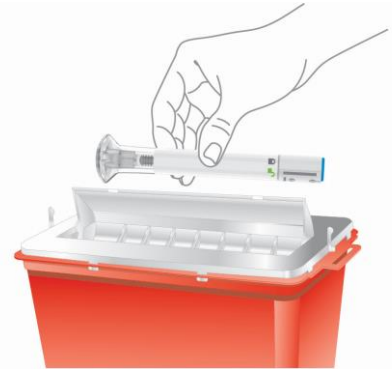
4 Repeat Steps 1 through Step 3 with the second Pen for a full dose.

- Use the second Pen right after using the first Pen.

Throwing away (disposing of) OMVOH Pens

Throw away the used Pens

- Put the used OMVOH Pens in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the OMVOH Pens in your household trash.



- If you do not have an FDA-cleared 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, and
 - properly labeled 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.
- For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** recycle your used sharps disposal container.

Commonly asked questions

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

A. Your Pen can stay at room temperature up to 86°F (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 before I twisted off the gray base cap?

A. **Do not** remove the gray base cap. Throw away (dispose of) the Pen and 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 gray base cap. Store the Pen in a safe place to avoid an accidental needlestick and contact 1-800-Lilly-Rx (1-800-545-5979) for instructions on how to return the Pen.

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.

If you have more questions about how to use the OMVOH Pen:

- Call your healthcare provider
- Call 1-800-Lilly-Rx (1-800-545-5979)
- Visit www.OMVOH.com



Scan this code to launch
www.OMVOH.com

Storing OMVOH Pens

- Store your Pens in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If needed, your Pens may be stored at room temperature for up to 2 weeks. **Do not** store above 86°F (30°C). Throw away (dispose of) OMVOH if not used within 2 weeks at room temperature. When OMVOH has been stored at room temperature, do not return it to the refrigerator.
- **Do not** freeze your Pens.
- Store your Pens in the original carton to protect from light until use.
- **Do not** microwave your Pens, or run hot water over them, or leave them in direct sunlight.
- **Do not** shake your Pens.
- Throw away (dispose of) your Pens if any of the above conditions are not followed.
- **Keep your Pens and all medicines out of the sight and reach of children.**

Read the Medication Guide for OMVOH inside this box to learn more about your medicine.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:

Eli Lilly and Company

Indianapolis, IN 46285, USA

US License Number 1891

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The OMVOH Pen meets the current dose accuracy and functional requirements of ISO 11608-1 and 11608-5.

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