

INSTRUCTIONS FOR USE
NEMLUVIO® [Nem LOO vee oh]
(nemolizumab-ilto)
for injection, for subcutaneous use

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

Read and understand these instructions before using the NEMLUVIO pen.

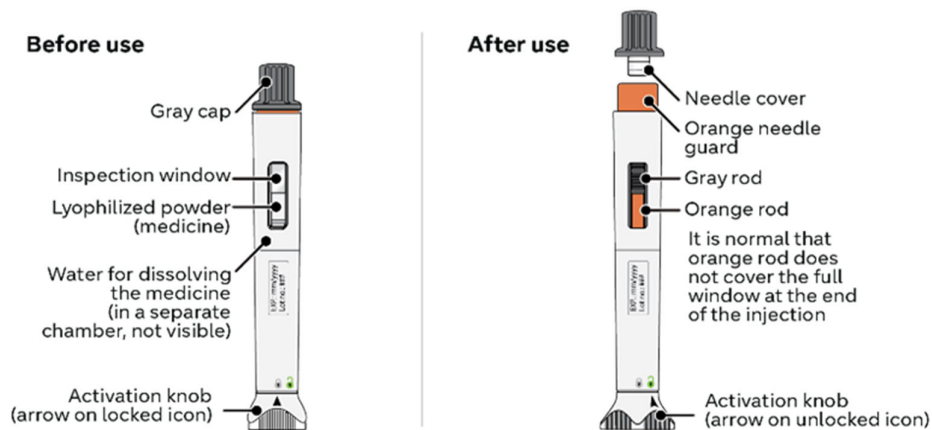
Do not inject yourself or someone else until you have been instructed how to inject NEMLUVIO.

Your healthcare provider will instruct you or your caregiver how to prepare and inject a dose of NEMLUVIO before you try to do it yourself the first time. Call your healthcare provider if you have any questions.

NEMLUVIO is supplied as a single-dose pen (called NEMLUVIO pen or pen in these instructions). It contains medicine (30 mg of lyophilized powder) in one chamber and water for dissolving the medicine in the other chamber. Before you can inject it, you must mix the lyophilized powder with the water for dissolving the medicine.

Device Overview

NEMLUVIO Single-Dose Pre-Filled Dual-Chamber Pen



Important Information

What you need to know before using the NEMLUVIO pen:

- Read all the instructions carefully before using the NEMLUVIO pen.
- **Mark your calendar** ahead of time to remember when to take NEMLUVIO.
- Follow all steps exactly as described. This makes sure that you get the correct dose of medicine.
- Make sure that the lyophilized powder is completely dissolved before injecting (Step 9).
- After dissolving, proceed right away with the injection to avoid any contamination or break down of medicine (degradation).
- **Do not** use the NEMLUVIO pen if it has been dropped on a hard surface or is damaged, cracked or broken.
- In some cases, your healthcare provider may prescribe 2 pens for a full dose. Use 1 NEMLUVIO pen after the other.
- To reduce the risk of accidental needle stick injury, each NEMLUVIO pen has an orange needle guard. After injecting the medicine, as you lift the pen from your skin, the orange needle guard locks into place to cover the needle (Step 16).
- When preparing the pen for injection, **do not** pull the gray cap. Instead, twist the gray cap until the orange needle guard pops up. Then, gently pull the cap off the orange needle guard (Step 12).
- Throw away (dispose of) the used NEMLUVIO pen right away after use in a sharps disposal container. See Section C: Throwing away (Disposing of) NEMLUVIO below.

Storage Information

- Store the NEMLUVIO pen in the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date.

- Store the NEMLUVIO pen in the original carton to protect it from light.
- The NEMLUVIO pen can be stored at room temperature up to 77°F (25°C) for a single period up to 90 days. Throw away (dispose of) the NEMLUVIO pen after the expiration date and any NEMLUVIO pen that has been left at room temperature longer than 90 days.
- After the NEMLUVIO pen lyophilized powder and water for injection are mixed (reconstituted), the NEMLUVIO pen must be used within 4 hours or thrown away (discarded).
- **Do not** heat or put the NEMLUVIO pen into direct sunlight.
- **Do not** freeze the NEMLUVIO pen.
- If the NEMLUVIO pen was heated or frozen, throw it away (dispose of it).

Keep the NEMLUVIO pen and all medicines out of the reach of children.

Traveling Information:

- Generally, you are allowed to carry pens with you on an airplane. Be sure to carry the NEMLUVIO pens with you in your carry-on luggage.

If you have any other questions refer to the Frequently asked questions (FAQs) on the back of this leaflet.

A. Preparing to inject NEMLUVIO

Step 1: Let NEMLUVIO reach room temperature

Injecting cold medicine might result in pain at the injection site. Take the **NEMLUVIO** carton out of the refrigerator and let it come to room temperature for 30 to 45 minutes before starting Step 2 (see **Figure A**).

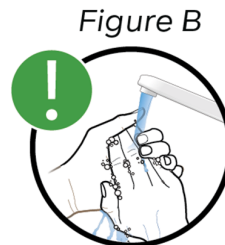
Do not:

- warm the pen with any heat source (such as microwave or direct sunlight). This might damage NEMLUVIO.
- directly expose the pen to liquids.



Step 2: Wash your hands

- To avoid contamination and infection, wash your hands with soap (see Figure B).
- Dry them properly.



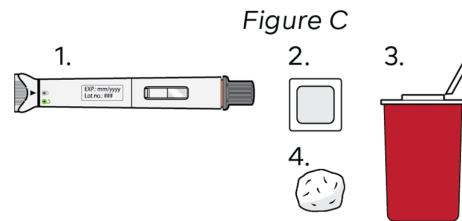
Step 3: Gather supplies (see Figure C)

- a. Remove the pen from the carton.
- b. Gather the following supplies on a clean, flat and well-lit surface:

1. Pen
2. Alcohol wipes*
3. Sharps disposal container*
4. Gauze pads or cotton balls*

*Items not included in the carton.

Note: In some cases, your healthcare provider may prescribe 2 pens. Use 1 pen after the other.



Step 4: Check the NEMLUVIO pen for the following:

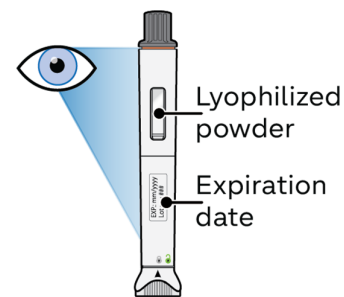
- a. Expiration date has **not** passed.
- b. The lyophilized powder is white and **not** dissolved (see Figure D).
- c. The pen has **not** been dropped and is not damaged or cracked.

Do not use the pen unless all conditions above are met.

If any condition is **not** met, **call: 1-866-735-4137**.

Throw away (dispose of) the pen and use a new one (see Section C: Throwing away (Disposing of) NEMLUVIO).

Figure D



Step 5: Activate the NEMLUVIO pen

Hold the pen upright and turn the activation knob to the right until it stops (see Figure E).

This starts the process of transferring water to the powder chamber.

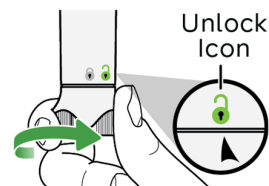
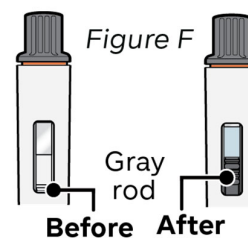


Figure E

Step 6: Wait until the gray rod stops moving

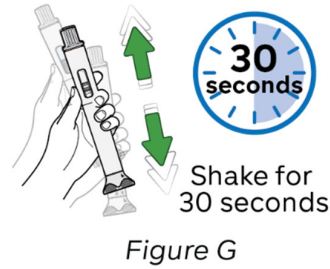
Watch the inspection window until the gray rod has stopped moving (see Figure F).

Do not shake the pen. Shaking the pen before the gray rod has completely stopped can affect the medicine dose.



Step 7: Dissolve the medicine

When the gray rod has completely stopped, shake the pen up and down for 30 seconds (see Figure G).

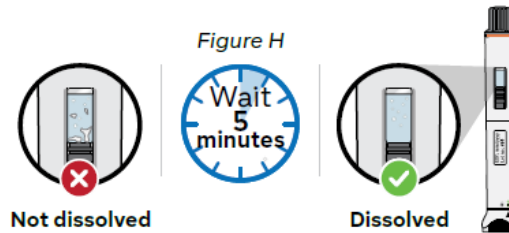


Step 8: Wait 5 minutes for bubbles to decrease

Wait for bubbles to decrease and the lyophilized powder to dissolve completely. This will take about 5 minutes (see Figure H).

Note: If the medicine has not dissolved completely, shake the pen up and down again for 30 seconds and then wait 5 minutes.

Note: It is normal for a small foam layer or a few small air bubbles to remain in the dissolved medicine.



Step 9: Check the medicine in the inspection window

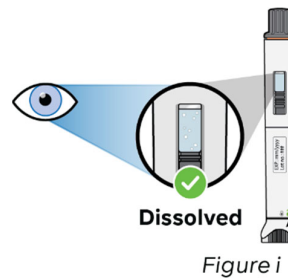
Check to see if the dissolved medicine:

- is clear and colorless to slightly yellow,
- does not contain particles (see Figure i).

Do not use the pen if the dissolved medicine is cloudy or contains any particles.


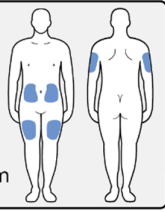
Throw away (dispose of) the pen and use a new one (see Section C: Throwing away (Disposing of) NEMLUVIO).

Note: After the medicine has dissolved, it must be used within 4 hours. During this time, it should be kept at room temperature (up to 77°F (25°C)). If you have not used it within 4 hours, throw it away (dispose of it).




B. Injecting NEMLUVIO

Step 10: Select one injection site (see Figure J)

<p>Note: When using a second pen, select a different injection site at least 1 inch away from the first injection site.</p> <p>Select the injection site using the following chart:</p> <p>Where not to inject:</p> <ul style="list-style-type: none">• near your waistline or about 2 inches around the navel.• into tender, bruised, red skin, or areas with scars or stretch marks.• twice into the same site (for example, within 1 inch).	<p>Self-Injection ●</p> <ul style="list-style-type: none">• Abdomen 2 inches away from navel• Upper thigh  <p>Injection by Caregiver ●</p> <ul style="list-style-type: none">• Abdomen 2 inches away from navel• Upper thigh• Outer, upper arm  <p>Figure J</p>
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Step 11: Clean the injection site (see Figure K)

<p>a. Always use a new alcohol wipe to clean the injection site. This avoids contamination and infection.</p> <p>b. Let the skin air dry.</p> <p>Do not:</p> <ul style="list-style-type: none">• touch the injection site after cleaning.• fan or blow air on the cleaned injection site.• reuse the alcohol wipe.	 <p>Figure K</p> <p>Alcohol Wipe</p>
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Step 12: Twist the gray cap

Do not:

- pull the gray cap when twisting to avoid damaging the device.
- touch the orange needle guard.

- a. **Hold** the pen **upright** (see Figure L, a).
- b. Twist the gray cap until the orange needle guard pops up (see Figure L, b).
- c. Gently pull the cap off the orange needle guard (see Figure L, c).
- d. After cap removal, please throw away (dispose of) the cap in a sharps disposal container (see Step 17).

Note: If the cap cannot be removed, refer back to **Step 5** and make sure the activation knob is turned completely to the right until it stops.

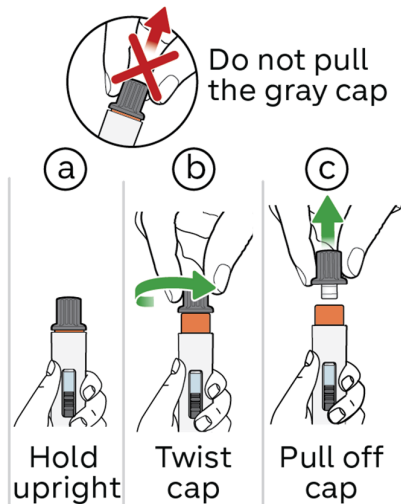


Figure L (a,b,c)

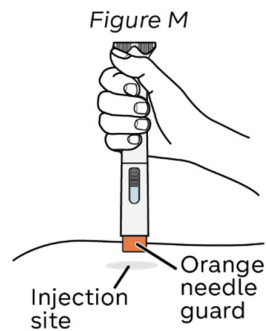
Step 13: Place the NEMLUVIO pen

Read Steps 13-16 before starting Step 13.

Note: Always inject the way your healthcare provider showed you.

Place the pen on the injection site vertically so that the orange needle guard is flat against the skin (see Figure M).

Note: Make sure you can easily see the inspection window during injection.



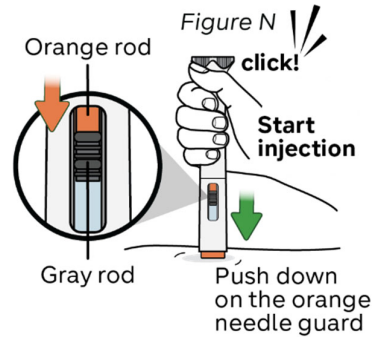
Step 14: Start injection and hold the NEMLUVIO pen on the skin

Gently push the pen down until the orange needle guard is completely pushed in.

The injection starts right away with a click (see Figure N).

The orange rod will begin to move down the injection window.

Do not lift the pen yet and keep pushing down.



Step 15: Inject for 15 seconds

Hold slowly and count to 15.

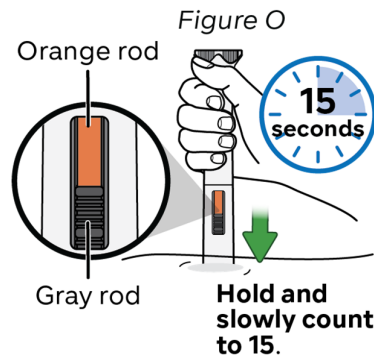
Check the inspection window to make sure the orange rod and gray rod have stopped (see Figure O).

This means the injection has been completed.

Note: It is normal that the orange rod does not cover the whole inspection window at the end of injection.

Do not lift the pen until the orange rod and gray rod have stopped moving.

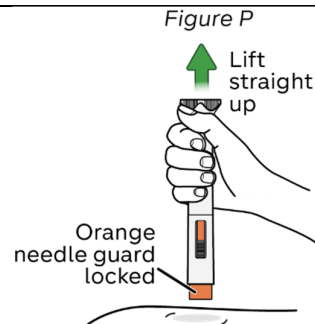
If the orange rod is not visible, please **call: 1-866-735-4137**. Throw away (dispose of) the pen and use a new one (see Section C for disposal details).



Step 16: Lift the NEMLUVIO pen up

- Lift the pen straight up from your skin. The orange needle guard locks into place to cover the needle (see Figure P).
- If there is bleeding, press a cotton ball or gauze over the injection site.

Do not rub the injection site.



Turn over to read about pen disposal and FAQs



C. Throwing away (disposing of) NEMLUVIO

Step 17: Throw away (dispose of) NEMLUVIO in a sharps disposal container

Avoid contact with the needle.

Throw away (dispose of) the used pen and the gray cap in a FDA cleared sharps disposal container right away after use (see Figure Q).

Do not:

- recap the pen after use,
- dispose of the NEMLUVIO pen and cap in your household trash,
- dispose of your used sharps disposal container in your household trash unless your community guidelines permit this,
- recycle your used sharps disposal container.

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 state or local laws about how you should dispose of used pens.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

<http://www.fda.gov/safesharpsdisposal>

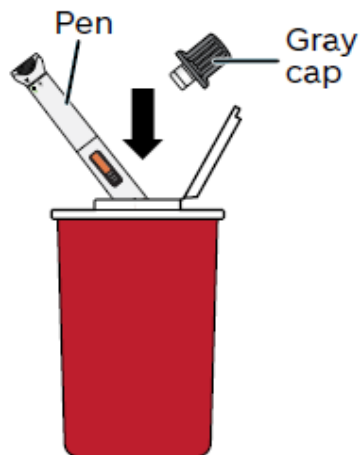


Figure Q

FAQs (Frequently asked questions)

Needle	Injecting the medicine
Where is the needle?	Why do I need to hold the pen upright while removing the gray cap?
<p>The needle is attached to the NEMLUVIO pen and covered by the gray cap.</p> <p>When you twist the gray cap, the orange needle guard pops up and keeps the needle covered until you inject.</p>	<p>Holding the NEMLUVIO pen with the gray cap upright helps prevent the medicine from leaking. It is normal to see a few drops of medicine inside the gray cap even when you hold the pen upright and remove the gray cap.</p>

For more information, please see the figures in Step 12 in this Instructions for Use.	
Dissolving the medicine	How do I know I injected myself the full dose of medicine in the pen?
How do I know if the medicine is fully dissolved?	To be sure you get the full dose of medicine, press and hold the NEMLUVIO pen against your skin.
To dissolve, shake the NEMLUVIO pen up and down until the white particles are no longer on the bottom, top, or sides. The dissolved medicine should look clear. Please refer to Step 9 in this Instructions for Use.	You will feel the needle go into your skin. Hold the NEMLUVIO pen against your skin for 15 seconds. This will allow enough time for all the medicine to go from the pen to under your skin.
After shaking the NEMLUVIO pen, look through both sides of the inspection window. You should not see any white particles along the bottom, top, or sides.	Only remove the NEMLUVIO pen when the orange rod and the gray rod have stopped moving.
It is acceptable to have small air bubbles or a small foam layer on top of the medicine. It does not harm you.	After removing the NEMLUVIO pen, look for the orange rod in the window as a way to tell that the dose has been given. If the orange rod does not appear, contact 1-866-735-4137.
If you see white particles in the medicine, it is not fully dissolved.	For details please refer to Step 15 in this Instructions for Use.
Storage	General Information
How should I store the NEMLUVIO pen?	Is it necessary to receive instructions on how to use the NEMLUVIO pen from a healthcare provider?
The NEMLUVIO pen should be stored in the refrigerator in its original carton to protect it from light.	Yes.
It can be stored at room temperature for up to 77°F (25°C) for a single period up to 90 days.	Do not inject the medicine if you did not receive a demonstration by your healthcare provider.
The device should not come in contact with liquids.	You should contact your healthcare provider right away to receive the information on how to use the NEMLUVIO pen.
Where do I find the expiration date?	Where can I get more information about using NEMLUVIO:
You can find the expiration date on the NEMLUVIO pen, it is labeled EXP YYYY-MM.	If you have other questions about how to use the NEMLUVIO pen: - Call your healthcare provider - Call 1-866-735-4137
What should I do if the medicine has been frozen?	
Do not use the NEMLUVIO pen if it has been frozen. Throw away (dispose of) the NEMLUVIO pen and use a new one.	

Manufactured by:
Galderma Laboratories, L.P.
Dallas, TX 75201

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

US License number: 2289

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