



Instructions for Use



CAREFULLY read and follow this
INSTRUCTIONS FOR USE

**This pen requires specific steps
before injection.**

NEMLUVIO[®] [Nem LOO vee oh]
(nemolizumab-ilto) injection
30 mg
Single-Dose Pre-Filled Dual-Chamber Pen

FOR SUBCUTANEOUS USE ONLY

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 shown how to inject NEMLUVIO.

Your healthcare provider will instruct you or your caregiver on 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.

Important Information

What you need to know before use

- 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).

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.

Preparing to Inject NEMLUVIO

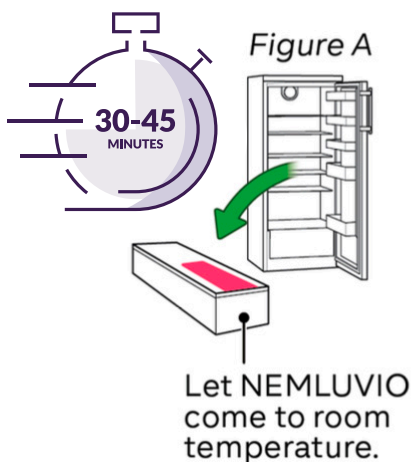
Step 1

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 a microwave or direct sunlight). This might damage NEMLUVIO.
- Expose the pen to liquids.



Step 2

Wash your hands

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

Figure B



Step 3

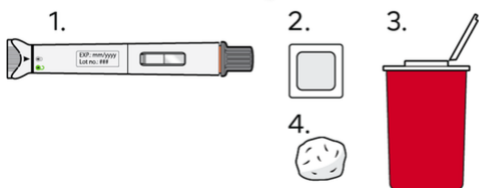
Gather supplies

- 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*

*These items not included in the carton.

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

Figure C



Step 4

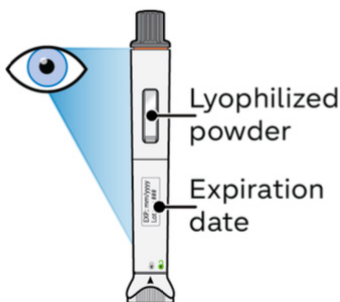
Check the NEMLUVIO pen for the following:

1. Expiration date has **NOT** passed.
2. The lyophilized powder is white and **NOT** dissolved (see Figure D).
3. 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 activation knob to the right until it stops (see Figure E). This starts the process of transferring water to the powder chamber.

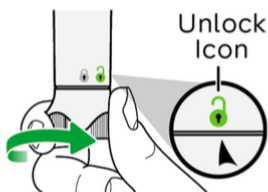


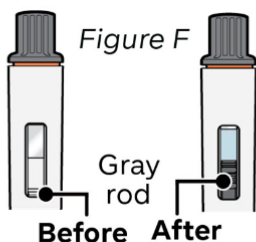
Figure E

Step 6

Wait until the gray rod stops moving

Watch inspection window until 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).

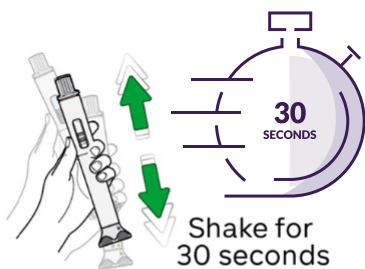


Figure G

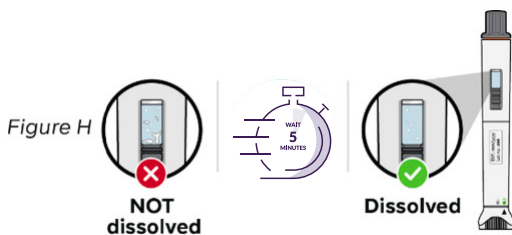
Step 8

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 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).

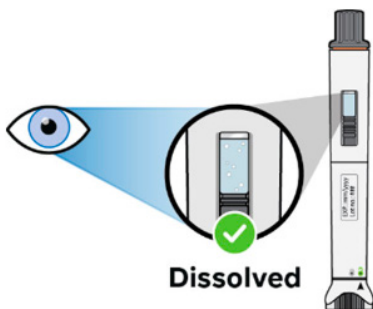


Figure I

Injecting NEMLUVIO

Step 10

Select one injection site (see Figure J)

Note: When using a second pen, select a different injection site at least 1 inch away from the first injection site.

Select the injection site using the following chart:

WHERE NOT TO INJECT:

- 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).

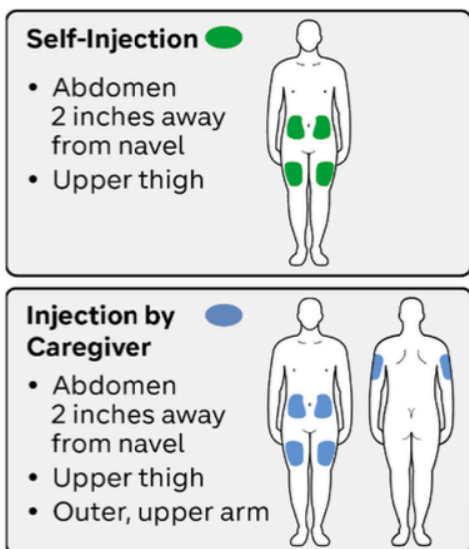


Figure J

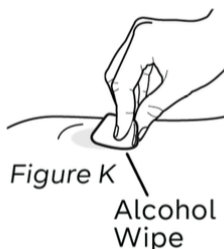
Step II

Clean the injection site (see Figure K)

- Always use a new alcohol wipe to clean the injection site. This avoids contamination and infection.
- Let the skin **air dry**.

DO NOT:

- Touch the injection site after cleaning.
- Fan or blow air on the cleaned injection site.
- Reuse the alcohol wipe.



Step I2

Twist the gray cap

DO NOT:

- Pull the gray cap by twisting to avoid damaging the device.
- Touch the orange needle guard.

1. **Hold** the pen **upright** (see Figure La)
2. Twist the gray cap until the orange needle guard pops up (see Figure Lb).
3. Gently pull the cap off the orange needle guard (see Figure Lc).
4. 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 activation knob is turned completely to the right until it stops.

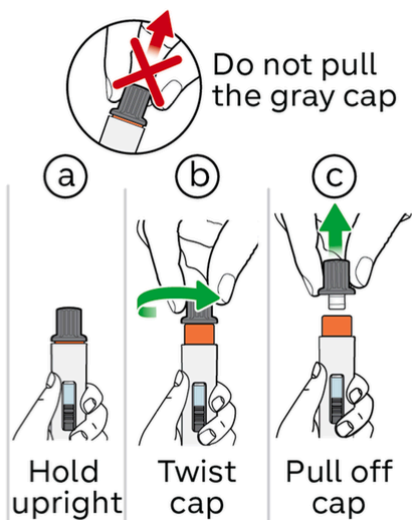


Figure L (a,b,c)

Step 13

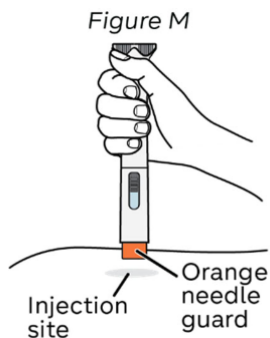
Place the NEMLUVIO pen

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

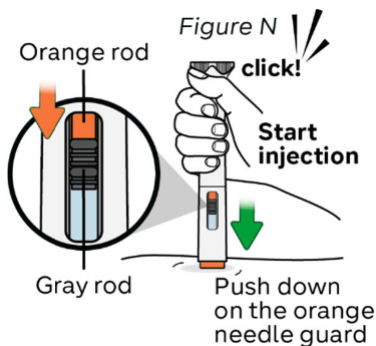
Start injection and hold the NEMLUVIO pen on the skin

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. 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 stopper have stopped (see Figure O).

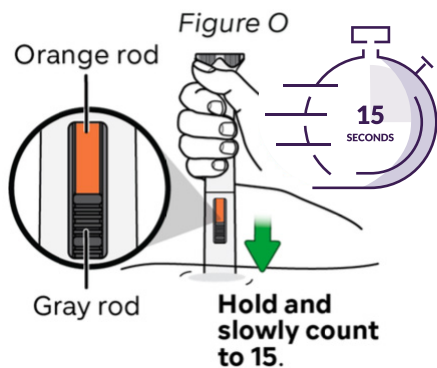
This means the injection has been completed.

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 orange rod and gray rod have stopped.

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 Step 17 for disposal details).



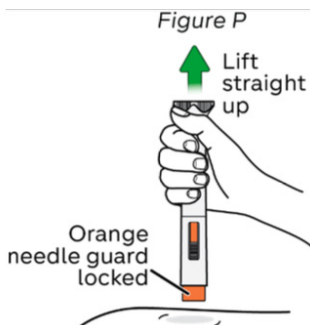
Step 16

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.



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 an 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.
- Closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out.
- Upright and stable during use.
- Leak-resistant.
- 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.

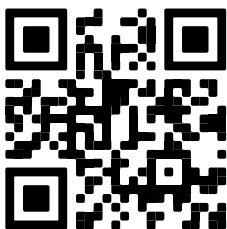
For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

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



Figure Q

GPS[★] for nemluvio™
GALDERMA PATIENT SERVICES



SCAN THE CODE