

Package leaflet: Information for the user



▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nemluvio is and what it is used for
2. What you need to know before you use Nemluvio
3. How to use Nemluvio
4. Possible side effects
5. How to store Nemluvio
6. Contents of the pack and other information

1. What Nemluvio is and what it is used for

What Nemluvio is

Nemluvio contains the active substance nemolizumab. Nemolizumab is a monoclonal antibody (a type of specialised protein) that blocks the action of proteins called interleukin (IL)-31. IL-31 plays a major role in causing the signs and symptoms of atopic dermatitis and prurigo nodularis.

What Nemluvio is used for

Nemluvio is used to treat adults and patients 12 years of age and older, weighing at least 30 kg, with moderate to severe atopic dermatitis (also known as atopic eczema) who can be treated with systemic treatments (a medicine given by mouth or injection). Nemluvio can be used with certain topical eczema medicines.

Nemluvio is also used to treat prurigo nodularis (PN), also known as chronic nodular prurigo (CNPNG).

How Nemluvio works

Using Nemluvio for atopic dermatitis or prurigo nodularis can improve the condition of your skin and reduce symptoms including itching and sleep disturbance.

In addition, Nemluvio helps improve symptoms related to pain and overall quality of life from your atopic dermatitis or prurigo nodularis.

2. What you need to know before you use Nemluvio

Do not use Nemluvio

- if you are allergic to nemolizumab or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, or you are not sure, ask your doctor, pharmacist or nurse for advice before using Nemluvio.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Nemluvio.

Allergic reactions

Very rarely, medicines can cause allergic (hypersensitivity) reactions. These reactions can occur shortly after you take Nemluvio, but also may happen later. You must look out for signs of these reactions (such as breathing problems, swelling of the face, mouth, and tongue, fainting, dizziness, feeling lightheaded (because of low blood pressure), hives, itching and skin rash) while you are using Nemluvio. Stop using Nemluvio and tell your doctor or get medical help immediately if you notice any signs of an allergic reaction. Such signs are listed in the beginning of section 4.

Vaccination

Talk to your doctor regarding your current vaccinations plan. See section "Other medicines and Nemluvio".

Children and adolescents

- Do not give this medicine to children with atopic dermatitis below the age of 12 years because the safety and benefits of Nemluvio are not yet known in this population.
- The safety and benefits of Nemluvio are not known in children with prurigo nodularis below the age of 18 years.

Other medicines and Nemluvio

Tell your doctor or pharmacist

- If you are using, have recently used or might use any other medicines.
- If you have recently had or are due to have a vaccination.

Pregnancy and breast-feeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The effects of this medicine in pregnant women are not known; therefore, it is preferable to avoid the use of Nemluvio in pregnancy unless your doctor advises to use it.
- If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you will breast-feed or use Nemluvio. You should not do both.

Driving and using machines

Nemluvio is unlikely to influence your ability to drive and use machines.

3. How to use Nemluvio

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Nemluvio is given and for how long

Your doctor will decide how much Nemluvio you need and how long you will use it for.

Recommended dose in adults and adolescents patients with atopic dermatitis (12 years of age and older)

For patients with atopic dermatitis, the recommended dose of Nemluvio is:

- An initial dose of 60 mg (two 30 mg injections) followed by 30 mg given every 4 weeks
- Based on how well the medicine works, your doctor may decide that you can have a dose every 8 weeks.

Use Nemluvio with topical eczema medicines. When your eczema has improved, your doctor may stop topical medicines.

Recommended dose in adults with prurigo nodularis (PN)

The recommended dose of Nemluvio for adults with prurigo nodularis is based on body weight:

Body weight of patient	Initial dose	Subsequent doses
less than 90 kg	60 mg (two 30 mg injections)	30 mg every 4 weeks
90 kg or more	60 mg (two 30 mg injections)	60 mg (two 30 mg injections) every 4 weeks

Injecting Nemluvio

Nemluvio is given as an injection under your skin (subcutaneous injection) into the front upper thigh or abdomen, avoiding a 5 cm area around the navel. If somebody else gives the injection, it can also be given into the upper arm. You and your doctor or nurse will decide if you can inject Nemluvio yourself.

It is recommended that you change the injection site with each injection. Nemluvio should not be injected into skin that is tender, inflamed, swollen, damaged or has bruises, scars or open wounds.

Before injecting Nemluvio yourself, you must have received proper instruction by a doctor or nurse. Your Nemluvio injection may also be given by a caregiver after proper instruction by a doctor or nurse.

The pre-filled pen must not be shaken.

Read carefully the instructions for use included at the end of this package leaflet before using Nemluvio.

If you use more Nemluvio than you should

If you use more Nemluvio than you should or the dose has been given too early, talk to your doctor, pharmacist or nurse.

If you forget to use Nemluvio

If you have forgotten to inject a dose of Nemluvio, talk to your doctor, pharmacist or nurse.

Give the Nemluvio injection as soon as possible, then continue with your original schedule.

If you stop using Nemluvio

Do not stop using Nemluvio without speaking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Nemluvio can cause serious side effects, including rare allergic (hypersensitivity) reactions such as anaphylaxis; the signs may include:

- breathing problems
- swelling of the face, mouth, and tongue
- fainting, dizziness, feeling lightheaded (low blood pressure)
- hives
- itching
- skin rash

Stop using Nemluvio and tell your doctor or get medical help immediately if you notice any signs of allergic reaction.

Other side effects

Common (may affect up to 1 in 10 people):

- Headache
- Hives
- Eczema (atopic dermatitis)

Uncommon (may affect up to 1 in 100 people):

- Swelling of the face, lips, mouth, throat or tongue (angioedema)
- Injection site reactions (i.e. redness, rash, pain, irritation and bruising)

Rare (may affect up to 1 in 1000 people):

- Swelling at the injection site

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nemluvio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original carton in order to protect from light.

If necessary, Nemluvio may be kept at room temperature (up to 25°C) for a single period of up to 90 days. Write the date first removed from the refrigerator in the space provided on the outer carton for the pen. Do not use Nemluvio beyond the expiration date or 90 days after the date it was first removed from the refrigerator (whichever is earlier).

Do not use this medicine if you notice that the powder is not white.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nemluvio contains

- The active substance is nemolizumab. Each pre-filled pen contains 30 mg of nemolizumab and 0.49 mL water for injection.
- The other ingredients are Sucrose, Trometamol, Trometamol hydrochloride, L-arginine hydrochloride, Poloxamer 188, Water for injections.

What Nemluvio looks like and contents of the pack

Nemluvio consists of a pre-filled pen enclosing a glass cartridge supplying a white powder and a clear liquid. The liquid is not visible from the inspection window before dissolving.

Nemluvio is available as 30 mg pre-filled pen in a pack containing 1 pre-filled pen or in multipacks containing 2 (2 packs of 1) pre-filled pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Evergreen House North
Grafton Place
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Manufacturers

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2400 Route Des Colles
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France

For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last revised in February 2025.

INSTRUCTIONS FOR USE

CAREFULLY read and follow Instructions for Use. This pen requires specific steps before injection.



These "Instructions for Use" contain 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.

In adolescents (ages 12 to 17 years old), it is recommended that Nemluvio be given by or under supervision of a trained adult or caregiver.

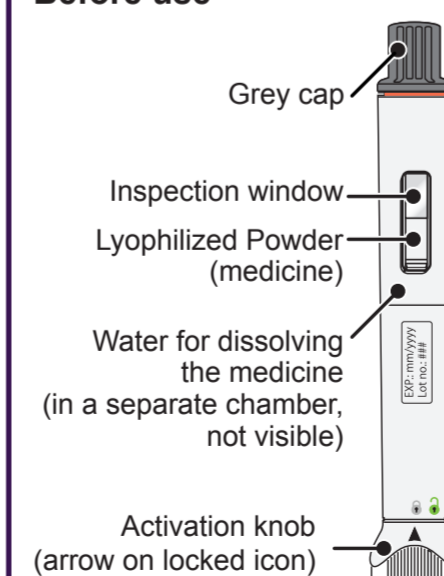
Your healthcare professional will instruct you or your caregiver on how to prepare and inject a dose of Nemluvio before you try to do it yourself the first time. Call your healthcare professional if you have any questions.

Nemluvio is supplied as a single-use, pre-filled dual-chamber 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 inject it, you must mix the lyophilized powder with the water for dissolving the medicine.

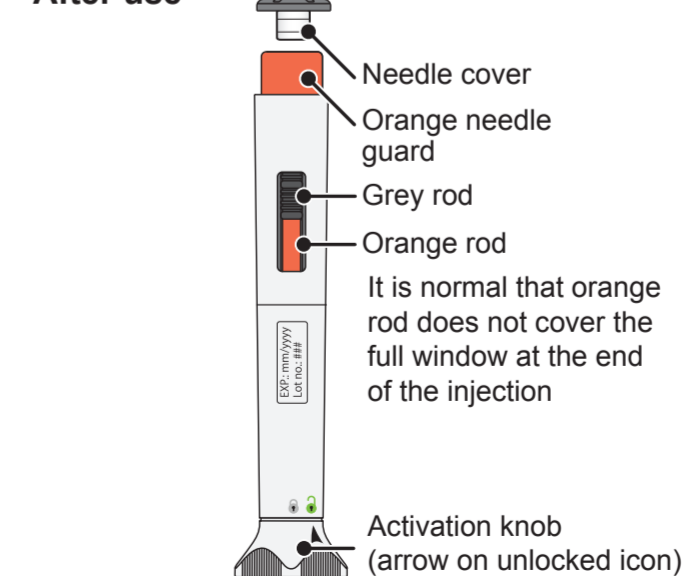
Device Overview

Nemluvio pre-filled dual-chamber pen

Before use



After use



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 prescribed dose of medicine.
- Make sure that the lyophilized powder is completely dissolved before injecting (Step 9).
- After dissolving, proceed as soon as possible with the injection to avoid any contamination or break down of medicine (degradation).
- **Do not** use the Nemluvio pen if it has been dropped or is damaged, cracked or broken.
- In some cases, your doctor may prescribe two pens. Use one Nemluvio pen after the other.
- To reduce the risk of accidental needle sticks, 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 grey cap. Instead, twist the grey cap until the orange needle guard pops up. Then, gently pull the cap off the orange needle guard (Step 12).
- Throw away the Nemluvio pen as soon as possible after use in a sharps disposal container. See Section "C: Throwing away Nemluvio" below.

Storage Information

- **Keep the Nemluvio pen and all medicines out of the sight and reach of children.**
- Store the Nemluvio pen in the refrigerator between 2°C to 8°C.
- The Nemluvio pen can be stored at room temperature up to 25°C for a single period of up to 90 days.
- Store the Nemluvio pen in the original carton to protect it from light.
- After reconstitution the Nemluvio pen must be used within 4 hours.
- **Do not** heat or freeze the Nemluvio pen.

Traveling Information

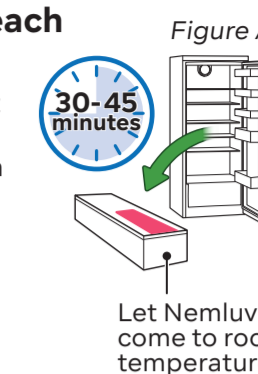
- Generally, you are allowed to carry pens with you on an airplane. Be sure to carry the Nemluvio pens with you in your carry-on luggage.

If you have any other questions, please refer to the FAQs and further information on the back of this package 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, direct sunlight). This might damage Nemluvio.
- directly expose the pen to liquids.

Step 2: Wash your hands

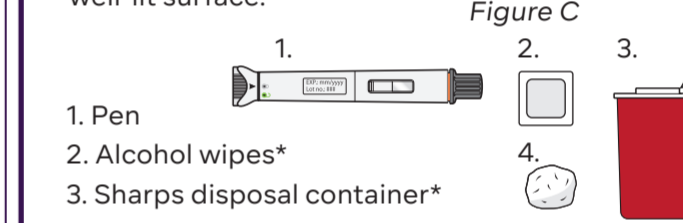
a. To avoid contamination and infection, wash your hands with soap (see **Figure B**).



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:



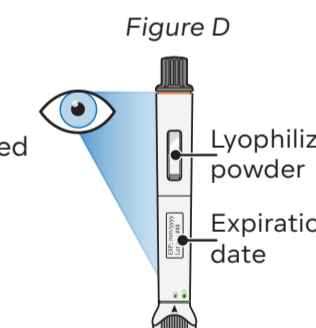
1. Pen
2. Alcohol wipes*
3. Sharps disposal container*
4. Gauze pads or cotton balls*

*Items not included in the carton.

Note: In some cases, your doctor will prescribe two pens. Use one 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.

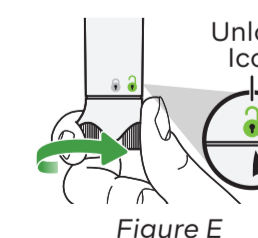


Do not use the pen unless all conditions above are met. If any condition is **not** met, throw away the pen and use a new one (see Section C: "Throwing away Nemluvio").

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.

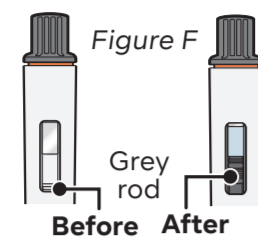


Turn over to continue reading about the pen injection steps and FAQs

A. Preparing to inject Nemluvio

Step 6: Wait until grey rod stops moving

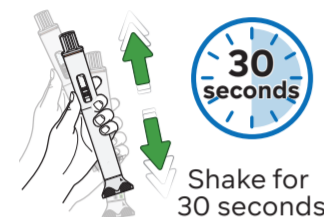
Watch inspection window until grey rod has stopped moving (see Figure F).



Do not shake the pen before the grey rod has completely stopped. You might get an incorrect dose of medicine.

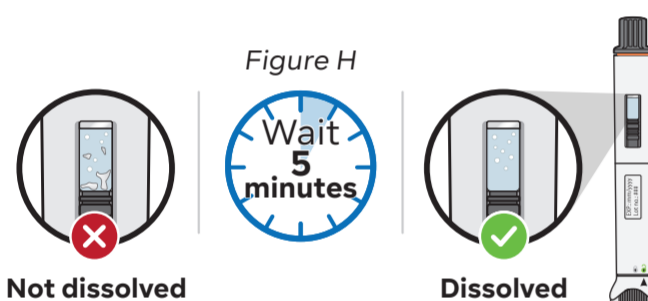
Step 7: Shake to dissolve the medicine

When the grey 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).

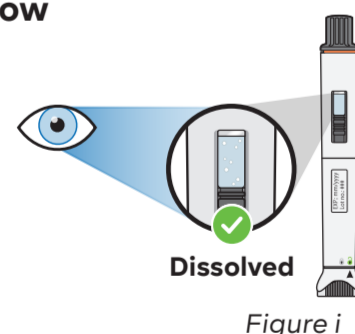


Note: If the medicine has not dissolved completely, shake again for 30 seconds and then wait 5 minutes.
Note: It is normal for a small foam layer or a few small air bubbles to remain in the dissolved medicine.

Step 9: Check the medicine in the inspection window

Check to see if the dissolved medicine:

- is clear and colourless 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 the pen and use a new one (see Section C: "Throwing away 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 25°C). If you have not used it within 4 hours, throw it away.

B. Injecting Nemluvio

Step 10: Select one injection site

(see Figure J)

When using a second pen, select a different injection site at least 2.5 cm away from the first injection site.

Select the injection site using the following chart:

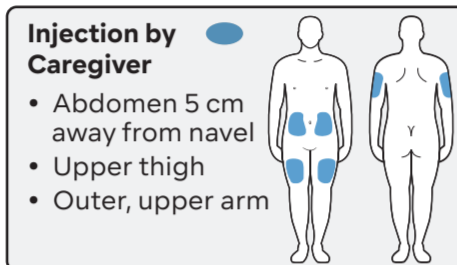
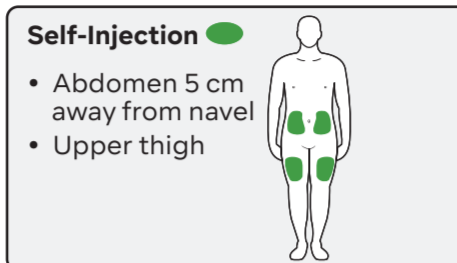


Figure J

Where not to inject:

- ✗** Near your waistline or about 5 cm around the navel.
- ✗** Into tender, bruised, red skin, or areas with scars or stretch marks.
- ✗** Twice into the same site (for example, within 2.5 cm).

Step 11: 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 12: Twist the grey cap

Do not:

- pull the grey cap when unscrewing to avoid damaging the device.
- touch the orange needle guard.

- Hold** the pen **upright** (see Figure L, a).

- Unscrew the grey cap until the orange needle guard pops up (see Figure L, b).

- Gently pull the cap off the orange needle guard (see Figure L, c).

- After cap removal, please throw away 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.

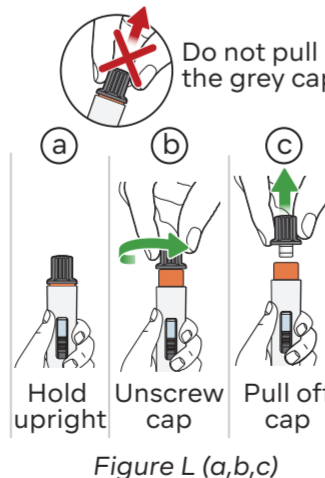


Figure L (a,b,c)

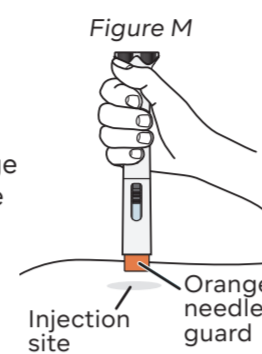
Step 13: Place the Nemluvio pen

Read Steps 13-16 before starting Step 13.

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

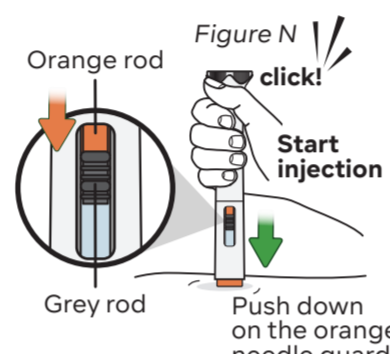
Place the pen on the injection site vertically so that the orange needle guard is flat against the skin (see Figure M).

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 orange needle guard is completely pushed in. The injection starts right away with a click (see Figure N).



Do not lift the pen yet and keep pushing down.

Step 15: Inject for 15 seconds

Hold and slowly count to 15.

Check inspection window to make sure orange rod and grey 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.

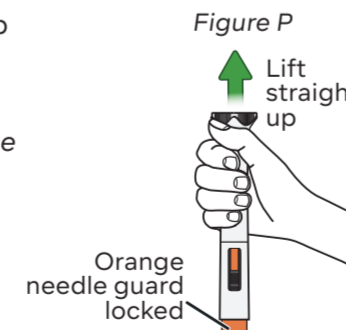
Do not lift pen until orange rod and grey rod have stopped moving.

If the orange rod is not visible please throw away the pen and use a new one (see Section C: "Throwing away Nemluvio").

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.

C. Throwing away Nemluvio

Step 17: Throw away the pen and the cap

Avoid contact with the needle.

Throw away the used pen and the grey cap in a sharps disposal container right away after use (see Figure Q).

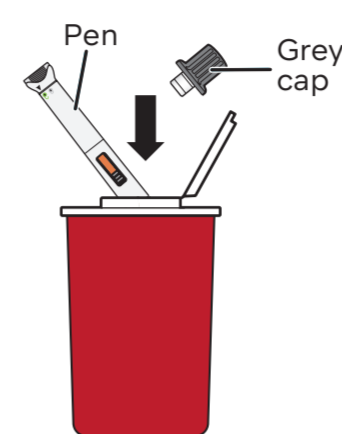


Figure Q

Do not:

- recap the pen after use.
- throw away the Nemluvio pen and cap in your household trash.
- recycle your used sharps disposal 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 used pens.

FAQs (Frequently asked questions)

Needle

Where is the needle?

The needle is attached to the Nemluvio pen and covered by the grey cap.

When you twist the grey cap, the orange needle guard pops up and keeps the needle covered until you inject.

For more information, please see the figures in Step 12 in the Instructions for Use.

Dissolving the medicine

How do I know if the medicine is fully dissolved?

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 the Instructions for Use.

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. It is acceptable to have small air bubbles or a small foam layer on top of the medicine. It does not harm you.

If you see white particles in the medicine, it is not fully dissolved.

Storage

How should I store the Nemluvio pen?

The Nemluvio pen should be stored in the refrigerator. It can be stored at room temperature up to 25°C for a single period of up to 90 days.

The device should not come in contact with liquids.

Where do I find the expiration date?

You can find the expiration date on the pen, it is labeled EXP MM/YYYY.

Do not use the Nemluvio pen past the expiration date.

What should I do if the medicine has been frozen?

Do not use the Nemluvio pen if it has been frozen. Throw away the Nemluvio pen and use a new one.

Injecting the medicine

Why do I need to hold the pen upright while removing the grey cap?

Holding the Nemluvio pen with the grey cap upright helps prevent the medicine from leaking. It is normal to see a few drops of medicine inside the grey cap even when you hold the pen upright and remove the grey cap.

How do I know I injected myself the full content of the pen?

To be sure you get the full content, press and hold the Nemluvio pen against your skin.

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.

Only remove the Nemluvio pen when the orange rod and the grey rod have stopped moving.

After removing the Nemluvio pen, look for the orange rod in the window as a way to tell that the content has been given. If the orange rod does not appear, throw away the pen and use a new one.

For details please refer to Step 15 in the Instructions for Use.

General Information

Is it necessary to receive instructions on how to use the Nemluvio pen from a healthcare professional?

Yes.

Do not inject the medicine if you did not receive a demonstration by your healthcare professional.

You should contact your healthcare professional to receive the information on how to use the Nemluvio pen.

Where can I get more information about using Nemluvio?

Call your healthcare professional.