

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 (CNPg).

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 syringe 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 syringe. 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, or if liquid is cloudy, or has particles in it.

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 single-use pre-filled syringe contains 30 mg of nemolizumab.

- The active substance is nemolizumab. Each pre-filled syringe 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 white powder and a clear liquid supplied in a glass pre-filled syringe with a separate needle with safety shield.

Nemluvio is available as 30 mg pre-filled syringe in a pack containing 1 pre-filled syringe.

Marketing Authorisation Holder

Galderma (U.K.) Limited
Evergreen House North
Grafton Place
London
NW1 2DX
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Manufacturers

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Seminariegatan 31
Helga Trefaldighet
752 28 Uppsala
Uppsala Lan
Sweden

Nuvisan France S.A.R.L.
2400 Route Des Colles
06410 Biot
France

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

This leaflet was last revised in January 2025.

INSTRUCTIONS FOR USE

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



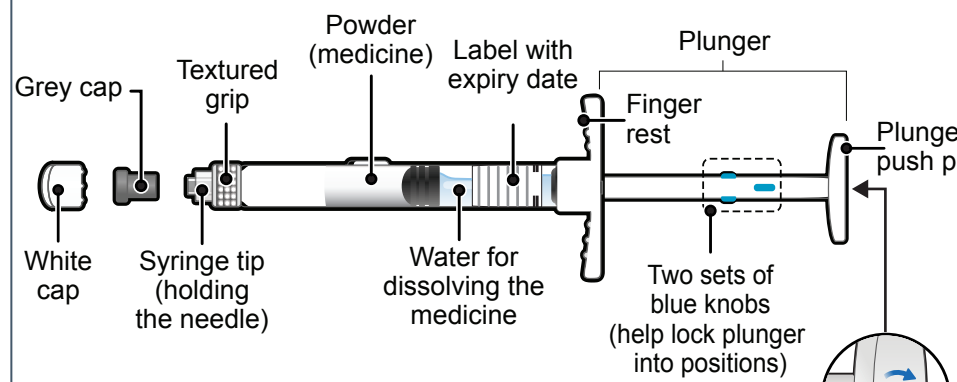
These "Instructions for Use" contain information on how to inject Nemluvio. **Read and understand these instructions before using the Nemluvio pre-filled dual-chamber syringe.** Do not inject yourself or someone else until you have been shown how to inject Nemluvio.

In adolescents (ages 12 to 17 years old), it is recommended that Nemluvio be administered 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.

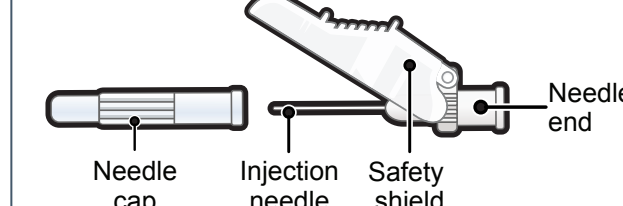
Call your healthcare professional if you have any questions. Nemluvio is supplied as a single-use pre-filled dual-chamber syringe (called "Nemluvio syringe" or "syringe" in these instructions). It contains medicine (30 mg of lyophilized powder) in one chamber and water for dissolving the medicine in 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 syringe



Injection needle



Important Information

What you need to know before use

- Read all the instructions carefully before using the Nemluvio syringe.
- **Mark your calendar** ahead of time to remember when to take Nemluvio.
- Follow all steps exactly as described. This ensures 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 syringe if it has been dropped or is damaged or cracked.
- **Do not** pull back on the plunger at any time.

- In some cases, your doctor will prescribe two syringes. Use one Nemluvio syringe after the other.
- To reduce the risk of accidental needle sticks, each syringe has a needle safety shield that needs to be manually flipped over the needle to cover the needle after the injection. Always take care when handling the syringe with needle.

- Throw away the syringe as soon as possible after use in a sharps disposal container. See Section C: "Throwing away Nemluvio" below.

Storage Information

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

Travelling Information

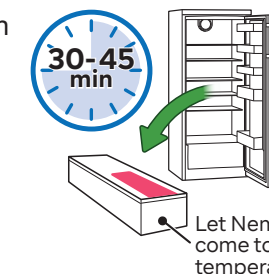
- Generally, you are allowed to carry the Nemluvio syringes with you on an airplane. Be sure to carry the Nemluvio syringes with you in your carry-on luggage.
- If you have any other questions, please refer to the FAQs and further information on the back of this package leaflet.

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).

Figure A



Step 2: Wash your hands

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

Figure B



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

Step 3: Gather supplies (see Figure C)

- Remove the syringe (by its body) and injection needle from the blister.
- Gather the following supplies on a clean, flat and well-lit surface:
 - Syringe
 - Injection needle
 - Alcohol wipes*
 - Sharps disposal container*
 - Gauze pads or cotton balls*

*Items not included in the carton.

Note: In some cases, your doctor will prescribe two syringes. Use one syringe after the other.

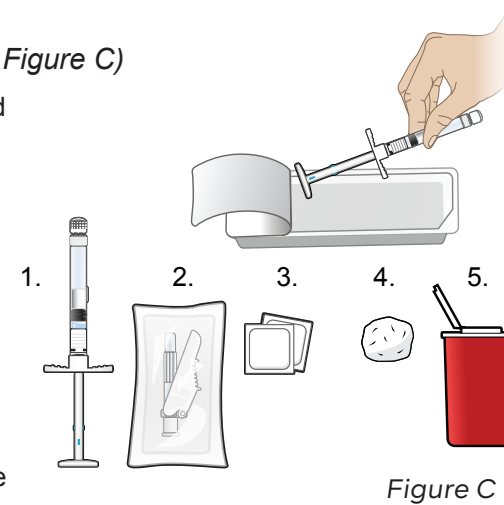


Figure C

Step 6: Attach the injection needle (see Figure F)

- Partially open the injection needle package to expose the needle end. Hold the needle package without touching the needle end.
- Hold the syringe with the syringe tip pointing upward.
- Hold the textured grip.
- Twist the syringe onto the needle end straight and tightly.
- Remove the injection needle package.
- Move the safety shield away from the needle and toward the syringe.

Do not remove the needle cap!

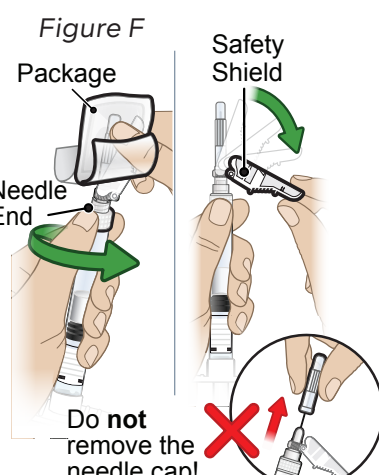


Figure F

Step 4: Inspect the Nemluvio syringe (see Figure D)

Check the syringe for the following:

- Expiration date has not passed.
- The lyophilized powder is white and not dissolved (see Figure D).
- The water for dissolving the medicine is clear, does not contain particles, and is not in contact with the lyophilized powder.
- The syringe has not been dropped and is not damaged or cracked.
- The white cap is connected and secure.

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

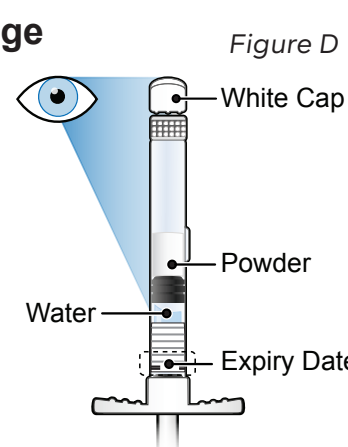


Figure D

Step 7: Dissolve the medicine (see Figure G (a, b, c))

- Hold the syringe tip upward (see Figure G a).
- Push the plunger until it locks on the first set of blue knobs (see Figure G b).

Do not pull plunger back out!

- Shake the syringe for 60 seconds (see Figure G c).

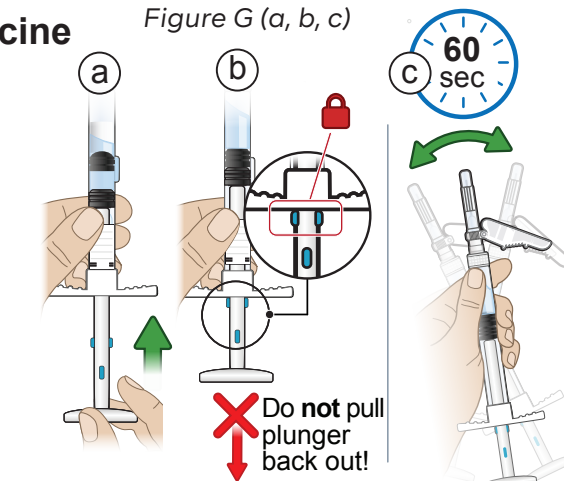


Figure G (a, b, c)

Step 8: Wait 5 minutes for bubbles to decrease (see Figure H)

- Lay down the syringe on a flat surface.
- 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 for 30 seconds and then wait 5 minutes again. **Note:** It is normal for a small foam layer or a few small air bubbles to remain in the dissolved medicine.

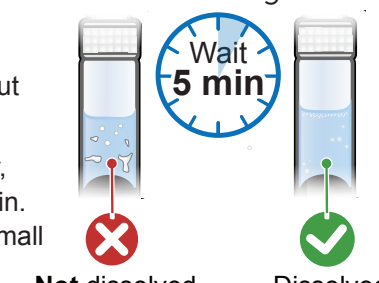


Figure H

Step 9: Inspect the medicine (see Figure I)

Check that the dissolved medicine:

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

Do not use the syringe if the dissolved medicine is cloudy or contains any particles. Throw away the syringe 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 (25°C). If you have not used it within 4 hours, throw it away.

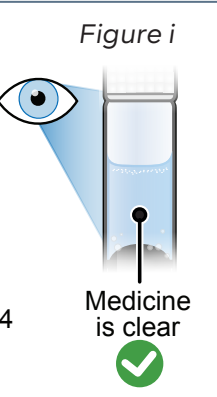


Figure I

Step 5: Remove the Nemluvio syringe's white cap and grey cap (see Figure E (a, b, c))

- With the syringe tip pointing upward, firmly hold by the textured grip. (see Figure E a)
- Twist off the white cap (see Figure E b).
- Pull off the grey cap (see Figure E c).

Do not touch the exposed syringe tip.

- Lay down the syringe on a flat surface.

Note: After removing the caps from the syringe, continue with the preparation steps.

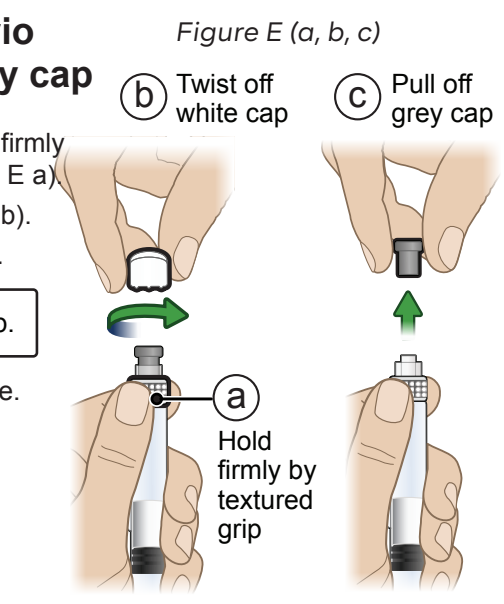


Figure E (a, b, c)

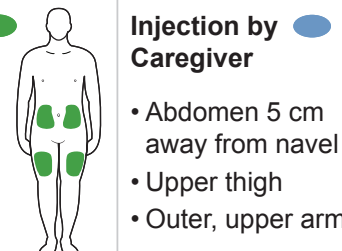
B. Injecting Nemluvio

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

Note: When using a second syringe, select a different injection site at least 2.5 cm away from the first site. Select the injection site using the following chart:

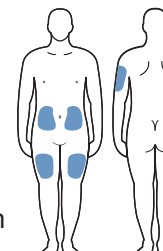
Self-Injection

- Abdomen 5 cm away from navel
- Upper thigh



Injection by Caregiver

- Abdomen 5 cm away from navel
- Upper thigh
- Outer, upper arm



Where not to inject:

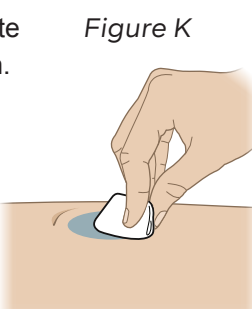
- Near your waistline or about 5 cm around the navel.
- Into tender, bruised, red skin, or areas with scars or stretch marks.
- Twice into the same site (for example within 2.5 cm).

Step 11: Clean the injection site (see Figure K)

- Always use a new alcohol wipe to clean the injection site (see Figure K). 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: Remove the needle cap (see Figure L (a, b))

- With the syringe tip pointing upward, hold the middle of the syringe body and needle cap. Be careful not to hold the plunger (see Figure L a).
- Gently pull the needle cap straight off (see Figure L b).
- Check that the needle is straight.

Do not:

- touch the needle or let the needle touch anything.
- try to recap the needle.
- use the syringe if the needle is bent.
- throw away the syringe and use a new one (see Section C: "Throwing away Nemluvio")
- leave the syringe unattended after removing the needle cap.

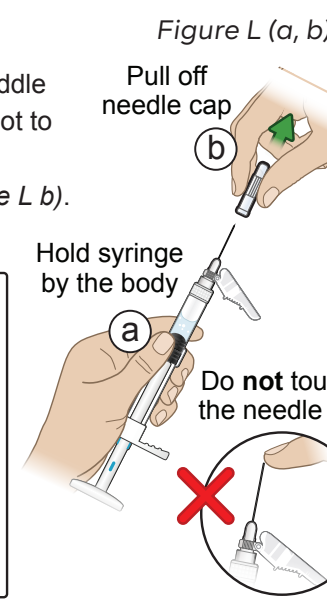


Figure L (a, b)

Step 13: Tap, turn, then push the plunger to prime injection (see Figure N)

- With the syringe tip pointing upward, tap the syringe with your fingertips to help air bubbles rise to the top.
- Turn the plunger 90 degrees (see Figure M).
- With the syringe tip pointing upward, slowly push the plunger further into the syringe until it locks on the second set of blue knobs (see Figure N).

Do not point the syringe tip downward, otherwise medicine could leak out.

Note: It is normal for a few small air bubbles to remain in the syringe.

Step 14: Position the plunger for injection (see Figure O)

With the syringe tip still pointing upward, turn the plunger 90 degrees again, to position the plunger for injection (see Figure O).

Do not push the plunger until the needle is inserted into the skin.

Step 15: Insert the needle at a 45° angle (see Figure P)

- Hold the syringe without touching the plunger.
- Gently pinch a fold of skin at the cleaned injection site with your other hand and hold it firmly.
- Insert the needle completely into the fold of skin at a 45-degree angle using a quick motion (see Figure P).

Do not:

- touch the plunger while inserting the needle.
- remove or tilt the syringe after inserting the needle.

Step 16: Inject medicine (see Figure Q)

Gently push the plunger all the way down until the syringe is empty and all medicine is delivered (see Figure Q).

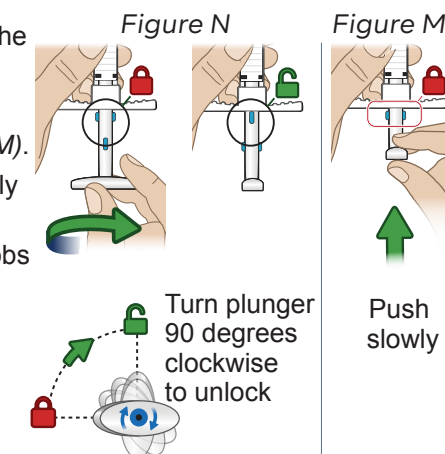


Figure N

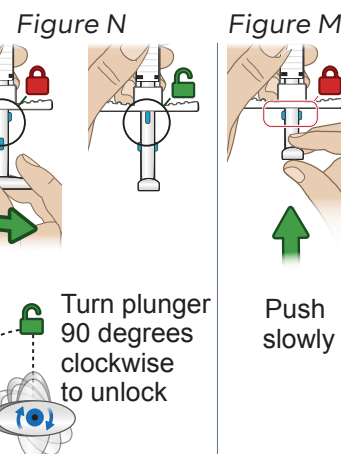


Figure M

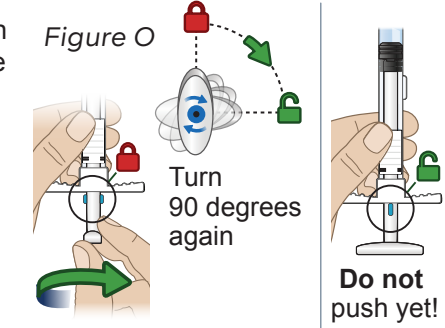


Figure O

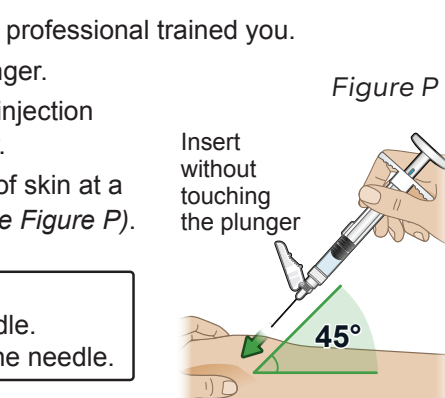


Figure P

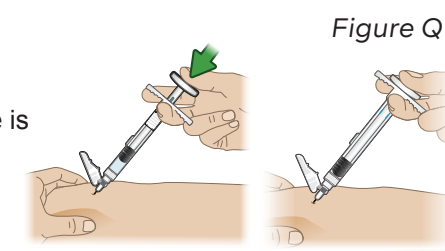


Figure Q

Step 17: Remove the syringe from the skin (see Figure R)

- While holding the syringe at the same angle, remove the syringe by pulling it out using two fingers (see Figure R).
- If there is bleeding, press a cotton ball or gauze over the injection site.

Do not:

- tilt the syringe while removing it.
- rub the injection site.

Step 18: Activate the safety shield (see Figure S)

Do not:

- put the needle cap back on.
- remove the needle from the syringe.

Push the needle safety shield against a flat surface to flip the safety shield over the exposed needle (see Figure S).

Note: If you have been prescribed a second syringe use the second syringe right after using the first syringe by repeating Steps 1-18.

C. Throwing away Nemluvio

Step 19: Throw away the syringe and caps (see Figure T)

- Throw away the used syringe with the attached needle, the needle cap, the white cap, and the grey cap in a sharps disposal container (closable, puncture-resistant container) right after use (see Figure T).

Do not:

- throw away of Nemluvio syringe with needle and caps in your household trash.
- throw away your used sharps disposal container 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 throw away your sharps disposal container. There may be local laws about how you should throw away used syringes. **If you have any questions, please talk to a healthcare professional who is familiar with Nemluvio.**

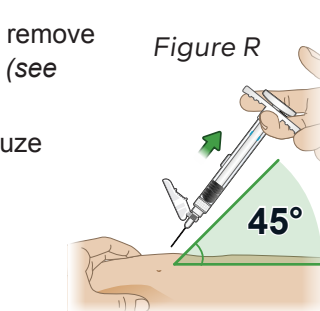


Figure R

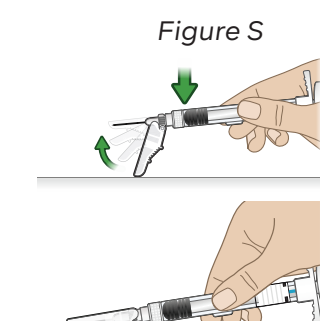


Figure S



Figure T

FAQs (Frequently asked questions)

Nemluvio syringe parts and handling

All the Nemluvio syringe parts are explained in the "overview" in the instructions for use.

What is the function of the blue knobs on the plunger?

The blue knobs are part of the locking mechanism of Nemluvio syringe. Please refer to Steps 13 and 14 or other parts of in the Instruction for Use or in this FAQ ("How do I unlock the syringe?") on how to unlock the syringe.

Why do I need to hold the Nemluvio syringe upright during certain steps? Once the medicine has been mixed, holding the syringe vertically with the needle upwards helps prevent the medicine from leaking.

Can I prime the Nemluvio syringe and save it for later use?

No, you cannot save it for later use. After priming the Nemluvio syringe you should complete the preparation steps and inject the medicine immediately.

How do I know I injected the full content of the syringe?

The injection is complete when the plunger push pad touches the finger rest, and the Nemluvio syringe is empty. The picture in Step 17 in the Instruction for Use shows what the syringe looks like when the intended dose has been injected.

Needle

What should I keep in mind when attaching the injection needle?

The Nemluvio syringe needs to be assembled with the injection needle before use. The injection needle is co-packaged. Be sure that you hold the syringe tip upwards when you remove the white cap and the grey cap, otherwise the medicine could leak. Do not touch the exposed syringe tip when you remove both caps. Please refer to Step 5 and 6 in the Instruction for Use for more details.

What should I do if the needle is bent?

Do not use the Nemluvio syringe if the needle is bent. Throw away the Nemluvio syringe as described in Step 19 in the Instruction for Use and use a new one.

Mixing the medicine

Do not use the Nemluvio syringe if the dissolved medicine remains cloudy or contains any particles. If this is the case, throw away the Nemluvio syringe and use a new one.

How do I know if the medicine is fully dissolved/mixed?

After dissolving the medicine (see Step 7 in the Instruction for Use) you should inspect the medicine. It is acceptable to have small air bubbles or a small foam layer on top of the medicine. It does not harm you. If the foam layer still produces small new bubbles, it is not yet completely dissolved. Please refer to Step 8 in the Instruction for Use and repeat the shaking procedure.

What if there are small chunks of powder in the liquid?

If you see any white powder chunks, the medicine is unmixed. There should not be any white powder chunks of the medicine in the syringe. Please refer to Step 8 in the Instruction for Use and repeat the shaking procedure.

Storage

How should I store the Nemluvio syringe?

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

Where do I find the expiration date?

You can find the expiration date on the syringe, it is labelled EXP MM/YYYY. Do not use the Nemluvio syringe past the expiration date.

What should I do if the medicine has been frozen?

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

Pushing the plunger

What if I cannot push the plunger?

It might be that the Nemluvio syringe is locked, and you need to unlock it by turning the plunger clockwise 90 degrees (a quarter turn). This can happen when you try to prime the Nemluvio syringe or when you try to inject the medicine (Steps 13, 14 and 15 in the Instruction for Use).

What if I cannot push the liquid out of the needle?

It might be that the Nemluvio syringe is locked, and you need to unlock by turning the plunger clockwise 90 degrees (a quarter turn). If the plunger is unlocked and you still cannot push it, the needle might be clogged. In that case the syringe cannot be used. Please throw away the Nemluvio syringe and use a new one.

How do I unlock the Nemluvio syringe?

There are two steps when you need to unlock the Nemluvio syringe: during priming and before injection (Steps 13, 14 and 15 in the Instruction for Use). The locking mechanism are the blue knobs on the plunger. By turning the plunger clockwise 90 degrees (a quarter turn), you lock or unlock the Nemluvio syringe.

What if I have accidentally removed the plunger?

If you have accidentally removed the plunger throw away the Nemluvio syringe and use a new one. This may happen by turning the plunger counterclockwise. The plunger should only be turned in the direction indicated on the push pad.

General information

Is it necessary to receive instructions on how to use the Nemluvio syringe 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 syringe.

Where can I get more information about using Nemluvio?

If you have other questions about how to use the Nemluvio syringe: Call your healthcare professional