

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Nemluvio?

Nemluvio contains the active ingredient nemolizumab. Nemluvio is used to treat adults and adolescents 12 years of age and older with atopic dermatitis (also known as atopic eczema) who can be treated with systemic treatments (by mouth or injection). Nemluvio is also used to treat adults with moderate-to-severe prurigo nodularis.

For more information, see Section [1. Why am I using Nemluvio?](#) in the full CMI.

2. What should I know before I use Nemluvio?

Do not use if you have ever had an allergic reaction to Nemolizumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines including scheduled vaccinations, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Nemluvio?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Nemluvio and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Nemluvio?

- Always take Nemluvio exactly as your doctor has told you.
 - Follow all directions given to you by your doctor, pharmacist or nurse.
- More instructions can be found in Section [4. How do I use Nemluvio?](#) in the full CMI.

5. What should I know while using Nemluvio?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Nemluvio.
Things you should not do	• You should not receive a live vaccine while taking Nemluvio. • Do not use Nemluvio in patients with atopic dermatitis under 12 years old, or patients under 18 years old with prurigo nodularis.
Driving or using machines	• Nemluvio is unlikely to influence your ability to drive or use machinery, but be careful until you know how it affects you.
Looking after your medicine	• Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original carton to protect from light. Do not shake. Do not expose to extreme heat. Nemluvio may be stored at room temperature, below 30°C for up to 90 days. • Remove from the fridge, 30 minutes prior to reconstituting. Once reconstituted, use within 4 hours. • 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.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Nemluvio may cause headaches, hives, eczema (atopic dermatitis), allergic type reactions and swelling at the injection site.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems (only applicable for Australian patients).

Nemluvio*

Active ingredient(s): [nemolizumab]

Consumer Medicine Information (CMI)

This leaflet provides important information about using Nemluvio. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Nemluvio.**

Where to find information in this leaflet:

1. [Why am I using Nemluvio?](#)
2. [What should I know before I use Nemluvio?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Nemluvio?](#)
5. [What should I know while using Nemluvio?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Nemluvio?

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

Nemluvio is used to treat adults and adolescents 12 years of age and older 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 or without topical eczema medicines.

Nemluvio is also used to treat adults with moderate-to-severe prurigo nodularis (PN), a chronic itchy condition associated with bumps also known as chronic nodular prurigo (CNPg).

2. What should I know before I use Nemluvio?

Warnings

Do not use Nemluvio if:

- you are allergic to Nemolizumab, or any of the ingredients listed at the end of this leaflet. If you think you may be allergic, or you are not sure, ask your doctor, pharmacist or nurse for advice before using Nemluvio.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have received, or are scheduled to receive any vaccinations

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant 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 you to use it.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You and your doctor should decide if you will breast-feed or use Nemluvio. You should not do both.

Vaccination

Talk to your doctor regarding your current vaccination plan.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you have had, or are due to have, a vaccination.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Nemluvio.

4. How do I use Nemluvio?

How much to take / use

- Always follow the directions given by your doctor, pharmacist or nurse.
- 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.
- For patients with **prurigo nodularis (PN)**
 - The recommended dose of Nemluvio for adults with prurigo nodularis is based on your current body weight.
 - If you are less than 90 kg, the recommended dose of Nemluvio is an initial dose of 60 mg (two 30 mg injections) followed by 30 mg every 4 weeks
 - If you are 90 kg or more, the recommended dose of Nemluvio is an initial dose of 60 mg (two 30 mg injections) followed by 60 mg (two 30 mg injections) every 4 weeks
- Follow the instructions for the [pen](#) and [syringe](#) provided and use Nemluvio until your doctor tells you to stop.

How to inject Nemluvio

- Nemluvio is given as an injection under your skin (subcutaneous injection) into the front upper thigh or abdomen, avoiding a 5cm area around the navel. If someone 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.
- Inject Nemluvio yourself only after you have been trained by your doctor or nurse. A caregiver may also give you your Nemluvio injection after proper training.
- DO NOT shake the pre-filled pen.
- Read carefully the instructions for use included in this document before using Nemluvio.

If you forget to use Nemluvio

Nemluvio should be used regularly at the same time each day of your schedule. If you miss your dose at the usual time, talk to your doctor, nurse or pharmacist. Give the missed dose as soon as possible, then continue with your next dose at the regular scheduled time.

If you use too much Nemluvio

If you think that you have used too much Nemluvio, or the dose has been given too early, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Nemluvio?

Things you should do

- Always follow your doctors' instructions carefully
- Tell any doctors, pharmacists and other health professionals who are treating you that you are being treated with Nemluvio.
- Tell your doctor immediately if you feel unwell after administering Nemluvio.
- If you are going to start another new medicine, tell your doctors, pharmacists and other health professionals that you are taking Nemluvio.
- If you become pregnant, or are planning to become pregnant, tell your doctor

Remind any doctor, dentist or pharmacist, or other healthcare professional, you visit that you are using Nemluvio.

Things you should not do

- Do not stop using Nemluvio without speaking to your doctor first.
- Do not administer Nemluvio to someone else, even if they have the same condition as you
- Do not use Nemluvio if it appears damaged.
- Do not use if the powder is not white, or if the solution appears cloudy, or has particles in it.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Nemluvio affects you.

Nemluvio is unlikely to influence your ability to drive and use machines but be careful driving or operating machinery until you know how Nemluvio affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol is unlikely to affect Nemluvio.

Looking after your medicine

- Store Nemluvio in the refrigerator between 2°C and 8°C.
- Nemluvio may be stored at room temperature, up to 30°C for no longer than 90 days
- DO NOT Freeze, or shake Nemluvio
- Keep Nemluvio in the original carton to protect from light

Follow the instructions in the carton on how to take care of your medicine properly.

When storing it below 30°C, store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Discard Nemluvio 4 hours after reconstitution. Discard Nemluvio after the expiry date marked on the package. Discard if stored at 30°C for more than 90 days.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date, or 90 days after taking it out of the fridge, whichever comes first.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Common (may affect up to 1 in 10 people): • Headache • Hives • Eczema (atopic dermatitis) Uncommon (may affect up to 1 in 100 people) • Injection site reactions (i.e. redness, rash, pain, irritation and bruising) • Blisters or fluid-filled spots on skin (signs of a skin condition called bullous pemphigoid) Rare (may affect up to 1 in 1000 people) • Swelling at the injection site.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Nemluvio can cause serious side effects including rare allergic (hypersensitivity) reactions such as anaphylaxis, the signs may include:	Stop using Nemluvio and call your doctor straight away, or go straight

• Breathing problems • Swelling of the face, mouth and tongue • Fainting, dizziness, feeling lightheaded (low blood pressure) • Hives • Itching • Skin rash	to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

Australia

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

Singapore:

If you suspect that you are experiencing a side effect after using Nemluvio and are concerned about it, inform your healthcare professional e.g. doctor, pharmacist or nurse about the symptoms.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Nemluvio contains

Active ingredient (main ingredient)	Nemolizumab
Other ingredients (inactive ingredients)	Sucrose, Trometamol, Trometamol hydrochloride, Arginine hydrochloride, Poloxamer, Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Nemluvio looks like

Pre-filled pen:

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 a 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.

Nemluvio's Australian Registration Number is

AUST R 444530

Who distributes Nemluvio

Galderma Australia Pty Ltd
Level 18, 1 Denison Street
North Sydney, NSW 2060

Ph 1800 800 765

This leaflet was prepared in August 2026.

Instructions for use

IMPORTANT: Read the package leaflet before use.

This pen requires specific steps before injection.

Nemludio

nemolizumab 30 mg

powder and solvent for solution for injection in pre-filled pen

Do not inject yourself or someone else until you have been trained by a healthcare professional on how to inject Nemludio.

Contact your healthcare professional if you have any questions.

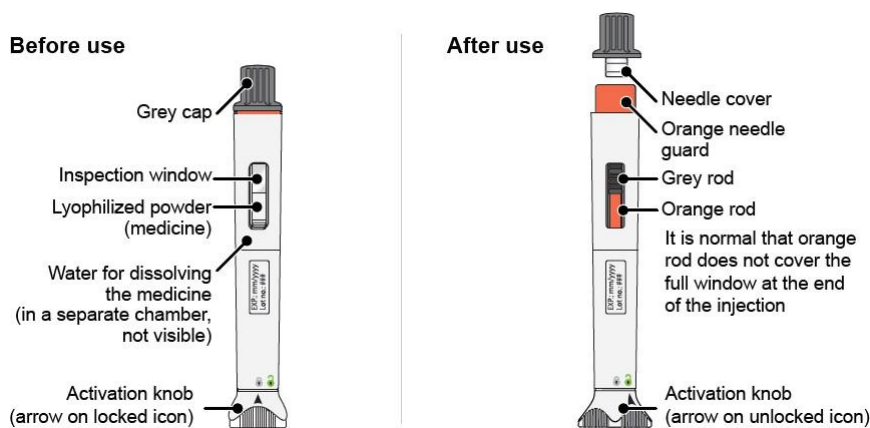
Nemludio is supplied as a single-use, pre-filled dual-chamber pen (called “Nemludio pen” or “pen” in these instructions).

The pen contains two chambers, one with medicine (30 mg of lyophilised powder) and one with water for dissolving the powder.

Before you can inject the medicine, you must mix the powder with the water, following the instruction-+ below.

Device Overview

Nemludio pre-filled dual-chamber pen



Important Information

What you need to know before use

- Read all the instructions carefully before using the Nemludio pen.
- **Mark your calendar** ahead of time to remember when to administer your next Nemludio dose.
- Follow all steps exactly as described. This makes sure that you get the correct dose of medicine.
- **Do not** use the Nemludio pen if it has been dropped on a hard surface or is damaged, cracked or broken.

Storage Information

- **Keep the Nemludio pen and all medicines out of the reach and sight of children.**
- Store the Nemludio pen in the refrigerator between 2°C to 8°C.
- **Do not** freeze or heat the Nemludio pen. If the Nemludio pen was frozen or heated throw it away and use a new one.
- Store the Nemludio pen in the original carton to protect it from light.
- The Nemludio pen can be stored in the original package at room temperature up to 30°C for a single period of up to 90 days. If removed from the refrigerator, write down the date of removal on the carton, and use Nemludio within 90 days.
- **Do not** use Nemludio if the expiration date has passed or 90 days after the date it was removed from the refrigerator (whichever is earlier)
- Once the reconstitution steps are completed, Nemludio must be used within 4 hours.

A. Preparing to inject Nemludio

Step 1: Let Nemludio reach room temperature

Injecting cold medicine might result in pain at the injection site.

Take the **Nemludio** carton out of the refrigerator and let it come to room temperature for 30 to 45 minutes before starting Step 2.

Do not:

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

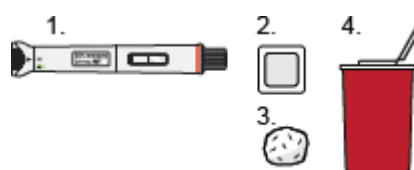
Note: In some cases, your doctor may prescribe two pens for use at the same time. If this applies to you, take out two pens and use one pen after the other.

Step 2: Wash your hands with soap and dry your hands properly

Step 3: Prepare the supplies

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

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



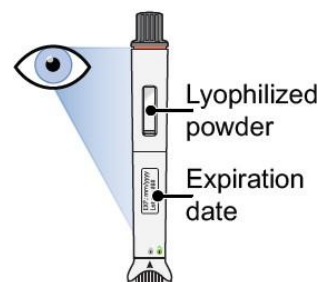
*Items not included in the carton.

Step 4: Check the Nemludio pen for the following:

- Expiration date has **not** passed.
- The lyophilized powder is white and **not** dissolved.
- 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 Step 13.5: "Throw away").

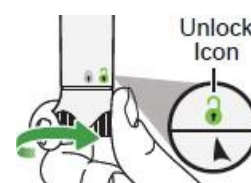
Figure D



Step 5: Activate the Nemludio pen

Hold the pen upright and turn activation knob to the right until it stops.

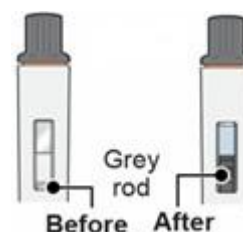
This starts the process of transferring water to the powder chamber.



Step 6: Wait until grey rod stops moving

Keeping the pen in the upright position, watch the inspection window until the grey rod has stopped moving.

Do not shake the pen before the grey stopper has completely stopped to enable accurate dosing.



Step 7: Shake to dissolve the medicine

When the grey rod has completely stopped, shake the pen up and down for 30 seconds.



Step 8: Wait 5 minutes for bubbles to decrease

Wait for bubbles to decrease and the lyophilised powder to dissolve completely. This will take about 5 minutes.

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

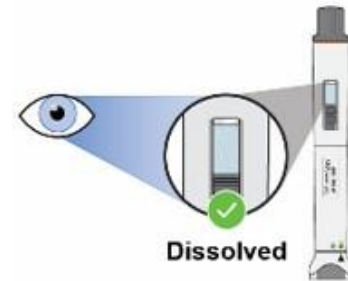
Check to see if the dissolved medicine:

- is clear and colourless to slightly yellow,
- does not contain particles.

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 Step 13.5 “Throw away”)

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 30°C). If you have not used it within 4 hours, throw it away.



B Injecting Nemludio

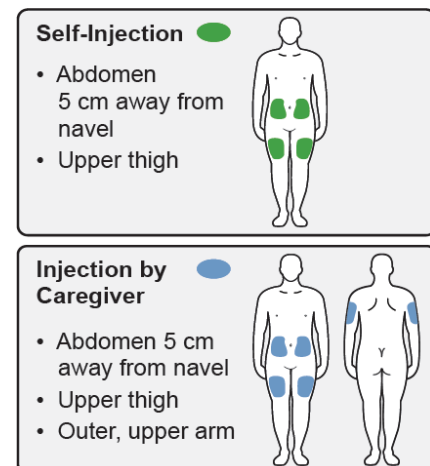
Step 10: Select one injection site)

You can self-inject in the abdomen or in the upper thigh.

A caregiver can also give the injection in the outer upper arm.

Where not to inject:

- Near your waistline or within 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

- 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.



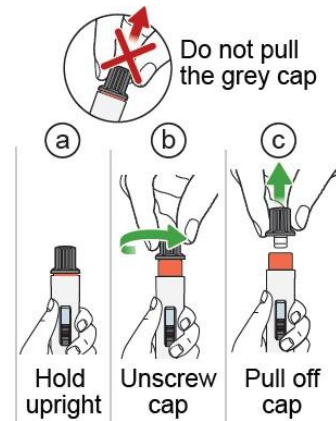
Step 12: Twist the grey cap off to expose the needle guard

- **Hold** the pen **upright** to avoid leakage.
- Unscrew the grey cap until the orange needle guard pops up.
- Gently lift the grey cap off the orange needle guard.
- After cap removal, please throw away the cap in a sharps disposal container (see Step 13.5 “Throw away”).

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.

Do not:

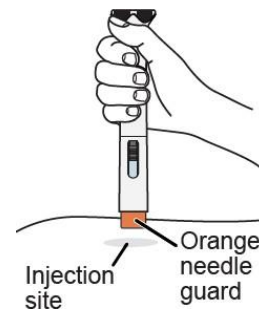
- pull the grey cap when unscrewing to avoid damaging the device.
- touch the orange needle guard.



Step 13: Injection of the medicine

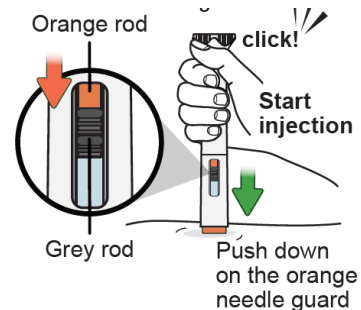
1. **Place the pen on the injection site vertically** so that the orange needle guard is flat against the skin.

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



2. **Gently push the pen down until orange needle guard is completely pushed in.** The injection starts right away with a click. The orange rod and grey rod should be moving

Do not lift the pen yet and keep pushing down and slowly count to 15.

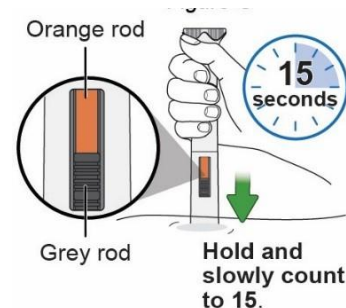


3. **Check inspection window** to make sure orange rod and grey stopper have stopped moving. This means the injection has been completed.

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.

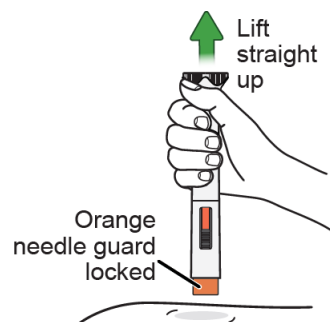
If the orange rod is not visible, please throw away the pen and use a new one (see Step 13.5: “Throw away”).



4. **Lift the pen straight up** from your skin.
The orange needle guard locks into place to cover the needle.

Note: If there is bleeding, press a cotton ball or gauze over the injection site.

Do not rub the injection site.



5. **Throw away** the used pen and the grey cap in a sharps disposal container right away after use. Avoid contact with the needle.

