



Nepexto[®]

etanercept 50 mg/1 mL auto-injector

Patient User Manual

Please note: not actual patients



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Please note: not an actual patient

About this Booklet

This booklet provides important information for patients and caregivers on how to use **Nepexto®** (etanercept 50 mg/1 mL) auto-injector correctly as it is intended.

Please always read the Consumer Medicine Information (CMI), this instruction manual and pack insert, as applicable, supplied with your medicine in full before use.

You should also speak to your healthcare provider (doctor or pharmacist) if you would like further information or if you have any concerns or questions about using **Nepexto®**.

This manual is also available from Lupin AU's website:
<https://lupin.com.au/nepexto/consumers>

Scan the QR code below or [Click here](#) to access the Consumer Medicine Information



Pack Details



Nepexto® is supplied as a pack of 4 auto-injectors, each containing 50 mg in 1 mL etanercept solution for injection for subcutaneous use.

Nepexto® auto-injector is an easy-to-use pen which can be self-administered.

The pack does not contain gauze pads, alcohol swabs, adhesive strips or sharps disposal containers.

Important Safety Precautions

DO NOT...

- ✗ shake the auto-injector containing **Nepexto**® solution. Shaking the solution will cause it to froth and the medicine may not work.
- ✗ take the needle cap off until you are ready to inject.
- ✗ put the needle cap back on the auto-injector once removed.
- ✗ twist or bend the needle cap while removing.
- ✗ use a heat source such as microwave or hot water to warm **Nepexto**® solution.
- ✗ use the auto-injector if it has been dropped onto a hard surface.
- ✗ use the auto-injector past the expiration date.
- ✗ forget to return any remaining auto-injectors in the carton to the refrigerator.

Instructions for use

Scan the QR code below to watch a step-by-step video tutorial on how to use your **Nepexto**® auto-injector.

You can contact aumarketing@lupin.com for a free fridge magnet with the QR code.

We recommend placing the magnet on your fridge so you can easily scan the QR code any time you want to revisit the instructions.

Alternatively, you can find written instructions in the subsequent pages.



Guide to using Nepexto® Auto-injector

The following instructions explain how to prepare and inject **Nepexto®**.

Please read the instructions carefully and follow them step by step. Please read the Consumer Medicine Information (CMI) each time you get a refill of your prescription. There may be new information.

The CMI recommends that the first injection should be performed under the supervision of a qualified health care professional. The ability of the patient to self-inject subcutaneously should be assessed.

You will be instructed by your healthcare provider (doctor, pharmacist or nurse) on the techniques of self-injection.

Do not attempt to administer an injection until you are sure that you understand how to prepare and give the injection.

The **Nepexto®** solution should not be mixed with any other medicine before use.



A: Setting up for an Injection

1. Select a clean, well-lit, flat working surface.

2. Collect the device and other materials.

- Take the **Nepexto®** carton containing the auto-injectors out of the refrigerator and place it on a flat, clean work surface together with one alcohol swab, cotton ball or gauze pad and adhesive strip.
- Remove one auto-injector from the carton and place it on your work surface.
- Return carton with remaining auto-injectors to the refrigerator.

3. Allow the solution to reach room temperature.

- Allow at least 30 minutes for the **Nepexto®** solution to reach room temperature before injecting.
This is important to make the medicine easier and more comfortable to inject.
- DO NOT remove the needle cap until you are ready to inject.
- DO NOT use a heat source such as microwave or hot water to warm Nepexto solution.



4. Inspect the auto-injector (refer to the diagram below).

- Always check the expiry date on the auto-injector label.
- DO NOT use the auto-injector past the expiration date.
- DO NOT use the auto-injector if it has been dropped onto a hard surface - components of the auto-injector may be broken.
- **Nepexto®** comes with a pink needle cap for protection. DO NOT use the auto-injector if the needle cap is missing or not securely attached.
- DO NOT remove the needle cap until you are ready to inject.

5. Inspect the solution in the auto-injector through the inspection window (refer to the diagram below).

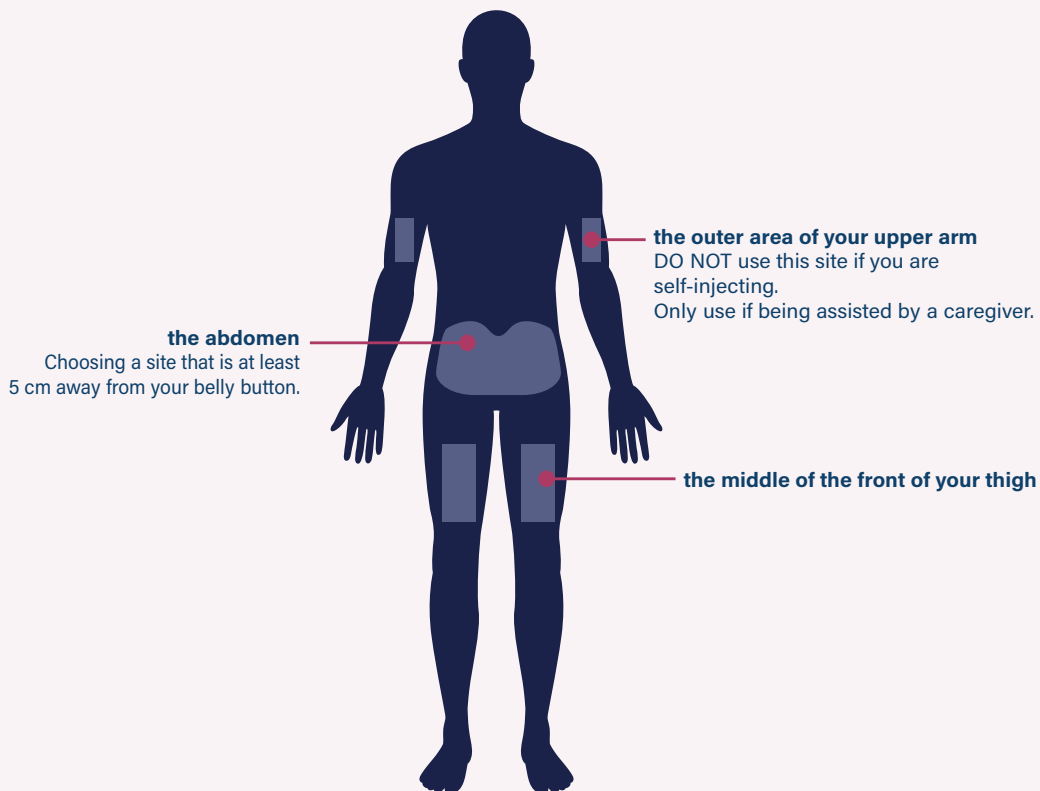
- The solution should be clear to opalescent, colourless to yellow and the liquid may contain trace levels of translucent to white particles. This appearance is normal for **Nepexto®**.
- DO NOT use the solution if it is discoloured, cloudy, or if particles other than those described are present.



B: Choosing an Injection Site

1. Nepexto® solution is for a subcutaneous injection.

The recommended injection sites for **Nepexto®** using an auto-injector include:



2. Use a different site for each new injection at least 3 cm from an old site.

- DO NOT inject into areas where the skin is tender, bruised, red, or hard.
- Avoid areas with scars or stretch marks.

3. If you have psoriasis, do not inject directly into any raised, thick, red, or scaly skin patches.

C: Injecting the Nepexto® solution



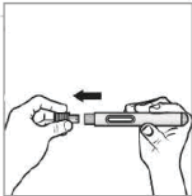
Step 1

Wash your hands with soap and water.



Step 2

Wipe the skin at the selected injection site with an alcohol swab using a circular motion and **DO NOT** touch this area before giving the injection. See "Choosing an injection site" on page 8 for guidance with choosing an injection site.



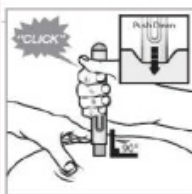
Step 3

Remove the pink needle cap by firmly pulling it straight off the auto-injector and dispose of it in the bin or sharps container. Ensure **NOT** to twist or bend the needle cap, as it may damage the needle. **NEVER** re-cap the needle.



Step 4

Once the cleared area of skin has dried, gently stretch the skin at the cleaned injection site with one hand and position the auto-injector approximately 90 degrees to the skin with the other hand. **DO NOT** pinch the skin. Stretching the skin creates a firm surface.



Step 5

Firmly press the auto-injector down into the site to start the injection. The auto-injector will click when the injection begins. Continue to hold the auto-injector firmly pressed into the site. The auto-injector will click a second time.



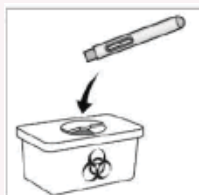
Step 6

After the second click, count slowly to 15 to make sure that the injection is complete.
DO NOT release pressure against the injection site before the injection is complete.
DO NOT move the auto-injector during the injection.



Step 7

Remove the empty auto-injector from the skin. The needle guard will completely cover the needle.
Check for the pink plunger rod in the window to confirm that the full dose has been delivered.



Step 8

The auto-injector is for single-use administration only and should **NEVER** be re-used.
 Dispose of the auto-injector in a sharps container or as instructed by your healthcare provider (doctor, pharmacist or nurse).

D: Injection site care

There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds to stop the bleeding.
 If needed, cover the injection site with a bandage. Do not rub the injection site.

If you have any questions or require further information, please talk with your healthcare provider (doctor, pharmacist or nurse).

Looking After Your Medicine

- ✓ Keep **Nepexto**® in a refrigerator where the temperature stays between 2°C and 8°C.
- ✓ **DO NOT** freeze.
- ✓ Keep it away from moisture, heat or sunlight.
- ✓ **DO NOT** store it in the bathroom, near a sink, in the car or on window sills.
- ✓ Store **Nepexto**® auto-injectors and in the carton to protect them from light.
- ✓ Keep it where young children cannot reach it.

FAQs

What if I am travelling and do not have access to a refrigerator?

Nepexto® can be stored out of the refrigerator (below 25°C) for up to 4 weeks.

If you have stored Nepexto® at room temperature for any period of time (even if returned to the refrigerator) you must use it within 4 weeks from the time you first took it out of the refrigerator, or else you must discard it.

What if Nepexto® was stored at a temperature that exceeds 25°C?

DO NOT use **Nepexto®** if it has been exposed to temperatures above 25°C or has been out of the refrigerator for more than 4 weeks.

What if I forget to use Nepexto® ?

If you miss your dose at the usual time, you should inject the next dose as soon as you remember if it is within 48 hours since the scheduled dose time.

If it is almost time for your next dose, ie. within 48 hours of your next dose, skip the dose you missed and take your next dose when you are meant to.

DO NOT take a double dose to make up for the dose you missed.

If you are uncertain what to do speak to your healthcare provider (doctor, pharmacist or nurse).

What if I use too much Nepexto®?

If you think that you have used too much **Nepexto®**, you may need urgent medical attention. You should immediately phone the Poisons Information Centre (by calling 13 11 26) for advice, 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.

What if the auto-injector doesn't work, or the solution doesn't appear as it should?

If the auto-injector doesn't work, return it to your pharmacy or contact Lupin AU Customer Service on (03) 9809 7900 (option 1).

Please note: not an actual patient

Getting started at home?

Supplemental support for **Nepexto**[®] is available online or on the phone.

Website

For more information and helpful resources, visit our website at <https://lupin.com.au/nepexto/consumers>

Phone Support

For general queries or for product quality complaints, please contact Lupin AU on (03) 9809 7900 (option 2) or by email at auinfo@lupin.com.

For any medical information queries or to report a side effect, please contact Biocon Biologics* on 1800 202 981 or by email at medical@maxxpharma.com.au.

Video Demonstration

Scan the QR code to access the tutorial video on how to inject **Nepexto**[®], or find it at <https://lupin.com.au/nepexto-video> or contact aumarketing@lupin.com for a free fridge magnet containing the QR code for easy access.



***Nepexto**[®] is a Biocon Biologics trademark, sponsored by Maxx Pharma and distributed in Australia by by Lupin AU (business name of Generic Health).

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Updated in July 2026
Material Code: LU-BIO-005

