

Teriparatide Lupin

Patient User Manual



Contents

Disclaimer -----	3
Important Information -----	4
Pack Details -----	5
Safety Instructions -----	6
Preparing Your Injection Pen Before First Use -----	7
Injecting Teriparatide Lupin -----	8
1. Preparing Yourself for Injection -----	8
2. Attaching the Needle -----	9
3. Dialling the Dose -----	9
4. Performing the Injection -----	10
5. Removing the Needle -----	11
6. Keeping the Injection Diary -----	11
Preventive Care -----	12
FAQs -----	13
Injection Diary -----	15
Getting Started at Home -----	16

Disclaimer

The educational materials provided in the following pages are intended for patients who have been prescribed a medicinal product supplied by Lupin AU (business name of Generic Health) by their treating doctors. By reading this booklet, you agree that you are a patient who is currently using or about to use a medicinal product supplied by Lupin AU for a condition that has been diagnosed by your treating doctor.

By continuing, you understand that the educational materials are provided herewith to assist you to use Lupin AU's product correctly as it is intended.

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

This manual is also available to download from Lupin AU's website:

<https://lupin.com.au/teriparatide/consumers>

Do not use Teriparatide Lupin if you have previously received teriparatide therapy for a total of 24 months. This total of 24 months therapy may have been made up of several shorter courses of teriparatide. If you are not sure if you have previously received teriparatide, speak to your doctor or pharmacist. **You will be required to sign your consent that you understand the 24-month lifetime limit.** Keep this consent form as you may need to show this to your doctor in the future. Your pharmacist may also ask to see your consent form.

Scan the QR code below for Consumer Medicine Information or find it at <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2024-CMI-01660-1&d=20260603172310101>.



Important Information

You will be required to sign a consent form understanding the 24-month lifetime limit.



Read the instructions on the package leaflet provided with the pen.



Use a new sterile needle for each injection.
Do not reuse needles.



You must not use Teriparatide Lupin if you have previously received the therapy for a total of 24 months.



If you have any questions, contact your doctor, pharmacist or caregiver.



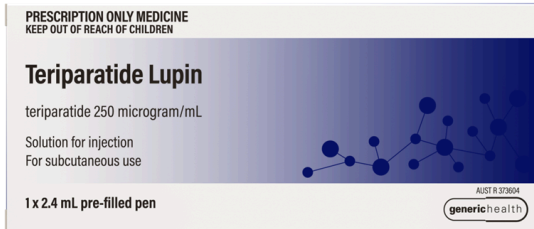
Do not share your pen as this may risk transmission of infectious diseases.



Pack Details

Teriparatide Lupin is a solution for injection supplied in a pen.

The pen contains medicine for once daily injection for 28 consecutive days.



Use a new needle for each injection.
Needles are not provided with the pack.

Consult your doctor or pharmacist about which needle is most suitable for you.

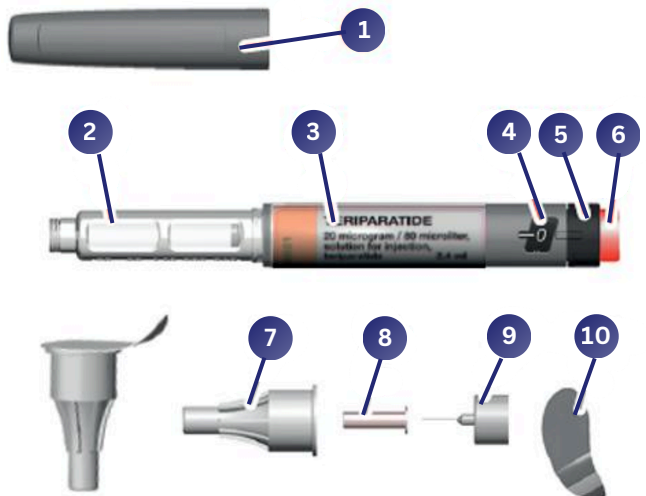
Refer to section below for the optimal needle sizes to use.

Recommended Needle Size: 31 gauge, 5 mm length, CE Certified.

If recommended needle size is not available, pen needles that meet the following specifications can also be used: 29-31 gauge; 5 mm to 12.7 mm in length; CE Certified.

Overview

- 1 Pen cap
- 2 Cartridge with medicine
- 3 Label
- 4 Dose window
- 5 Dose knob
- 6 Dose activator
- 7 Large outer cap
- 8 Small inner cap
- 9 Needle
- 10 Seal foil



Safety Instructions

Use of pen

CHECKLIST



Check pen label to ensure you use the right medicine.



Check the expiry date.



Check the solution: it must be clear, colourless & free of particles.

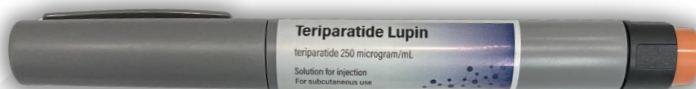
Do not use the pen for more than 28 injections. Note the 1st day & the 28th day of injection.



Teriparatide Lupin must be administered using the injection pen provided. Do not transfer to a syringe.



Anyone who is blind/visually impaired must seek help from a support person or carer.



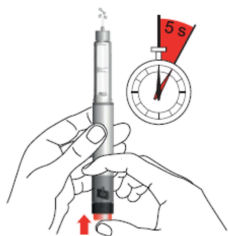
Instructions for Use

Preparing your Injection Pen Before First Use



1. **Before the FIRST injection with a new pen, you must prepare your pen as described here.**
2. **This step only needs to be performed once before use for each new injection pen.**

Follow Step 2 (Attaching the Needle) and Step 3 (Dialling the Dose) below under “Injecting Teriparatide Lupin” to prepare your pen.



Prime your injection pen by:

- holding pen with needle up;
- push the dose activator to the hard stop and hold for 5 seconds; and
- collect the expelled liquid with a tissue.



After the liquid is expelled, make sure the figure “0” is fully visible and centred in the dose window, the white mark is aligned in the window notch and the debossed marks of dose knob and pen body are aligned.

Remove the needle as described in Step 5 (Removing the Needle) below. Always remove needle after preparation of pen (and immediately after each use) as it poses a risk of being contaminated.

Your pen is now ready for your first injection.

Instructions for Use

Injecting Teriparatide Lupin



Ensure you have followed the steps under “Preparing Your injection Pen Before First Use” before your first injection.

You only need to prepare your pen for use once.



1. Preparing yourself for Injection

(Step 1)

Wash your hands before every injection.

(Step 2)

Prepare the injection site (on thigh or abdomen) as directed by your doctor, pharmacist or caregiver. Clean the chosen area with an alcohol wipe.

Use a new needle for every injection because a new needle is sharp and allows an almost pain-free injection.

A used needle poses a risk of being clogged or contaminated.

Instructions for Use

2. Attaching the Needle

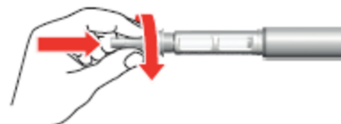


(Step 1)

Remove pen cap.

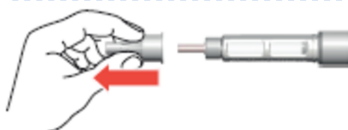
(Step 2)

Take a new needle and remove the seal foil from the needle cap.



(Step 3)

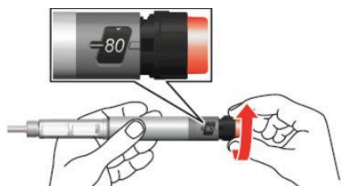
Attach the needle with a large outer cap and screw the large outer cap clockwise until hard stop.



(Step 4)

Remove the large outer cap from the needle and keep it for later use.

3. Dialling the Dose



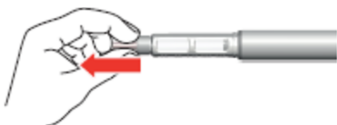
(Step 1)

Turn the dose knob to the hard stop.

Keep turning past the directional arrow.

Make sure the figure “80” is fully visible and centred in the dose window with the white mark aligned in the window notch.

NOTE: The “80” refers to the dose of 80 microlitres which contains 20 micrograms of teriparatide.



(Step 2)

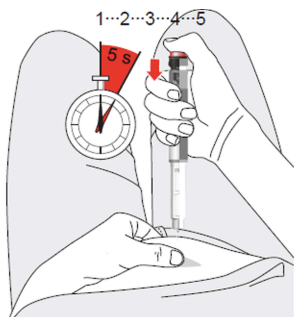
Remove small inner cap from the needle and dispose of it.

Instructions for Use

4. Performing the injection

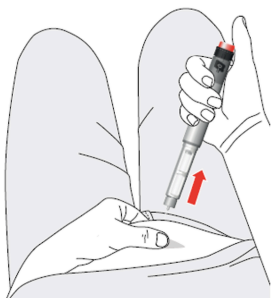
(Step 1)

Gently hold a fold of skin from thigh or abdomen.



(Step 2)

Insert the needle preferably at a 90 degree angle at the prepared injection site. Push the dose activator to the hard stop and hold for 5 seconds. Count up slowly to 5.



(Step 3)

Pull out the needle from the skin.



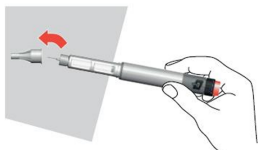
(Step 4)

Confirm dose. Make sure the figure "0" is fully visible and centred in the dose window, the white mark is aligned in the window notch and the debossed marks of dose knob and pen body are aligned.

Instructions for Use

5. Removing the needle

Always remove needle immediately after each use of the injection pen as it poses a risk of being contaminated.



(Step 1)

Carefully push the needle into the large outer cap kept aside before in Step 4. To prevent injury, do not touch the needle directly.



(Step 2)

Unscrew the needle by turning the large outer cap counter clockwise and pull needle from pen.

(Step 3)

Dispose of the needle in a puncture safe container which can be obtained from your pharmacy or from your caregiver.

(Step 4)

Re-attach the pen cap to the injection pen.

6. Keeping the injection diary



(Step 1)

Refer to the Injection Diary at the end of these Instructions for Use. (Page 15)

(Step 2)

Note the current date of injection next to the relevant day, and calculate the date of the 28th injection, if not already done so, in the Injection Diary.

Preventive Care



Store the pen in the refrigerator, preferably in a door compartment. Only take the pen out of the refrigerator for use.



Don't store the pen next to the back wall of the refrigerator or in the freezer. The medicine becomes unusable if frozen.



Keep pens and needles out of the reach of children.

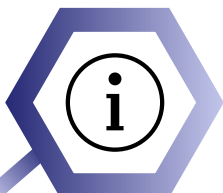


Always close the pen with a pen cap.



The pen must be disposed off, as directed by your physician or pharmacist, on the day of the last injection (as per the Injection Diary).

If your pen has been left out of the refrigerator for a period of time, don't throw it away. Put the pen back in the refrigerator & contact your physician, pharmacist, or caregiver.



Do not store the pen with a needle attached. Doing this may cause air bubbles to form in the medicine cartridge.



Dispose of the pen once all injections have been taken, even if there is solution remaining in the cartridge.



Attach the pen cap before disposal. Don't dispose the pen with the needle attached.

FAQs

What to do if small air bubbles are visible in the cartridge?

You can use your pen without any concern. Small air bubbles will not affect the dose or cause any harm.

What to do if solution is not clear, colourless or free of particles?

Do not use the injection pen. Return it to your pharmacist, or contact Lupin AU Customer Service on 03 9809 7900, Option 1.

What to do if, while preparing the pen for first use, no solution is expelled?

Perform the “Dialling the Dose for First Injection” step again. Continue until a few drops of solution are expelled.

What to do if the dose activator is blocked or you have not injected the full dose?

Do not give a second injection the same day. Proceed with your regular injection the next day. Before injecting, make sure you turn the dose knob to the hard stop and the figure “80” is fully visible and centred in the dose window with the white mark aligned in the window notch.

What to do if, after injection, a small amount of solution is visible on the needle?

This is normal and can be expected. The pen can continue to be used.

FAQs

What to do if only a partial injection occurred and the full dose has not been injected?

Do not give a second injection the same day. Proceed with your regular injection the next day. Before injecting, make sure you turn the dose knob to the hard stop and the figure “80” is fully visible and centred in the dose window with the white mark aligned in the window notch.

Do not stop turning the dose knob at the arrow – continue turning until the “80” is fully visible.

NOTE: The “80” refers to the dose of 80 microlitres which contains 20 micrograms of teriparatide.

What to do if you accidentally tried to inject without a needle attached?

Attach a needle. You will observe some drops coming out. The pen is now ready for use again. Set the dose and inject.

What to do if the injection pen is damaged or spillage from the pen is observed when not in use?

Do not use the injection pen. Return it to your pharmacist, or contact Lupin AU Customer Service on 03 9809 7900, Option 1.

What to do if the needle cannot be attached?

Ensure the correct needle type is being used (refer to the “Instructions for Use” in the Consumer Medicine Information, or “Pack Details” above, or the “Preparing your injection pen before first use” video).

Try another needle instead. If the second needle cannot be attached either, contact Lupin AU Customer Service on 03 9809 7900.

What to do if the needle is broken, curved or kinked?

Discard and use another needle.

Injection Diary

Note the current date of injection next to the relevant day, and calculate the date of the 28th injection in the injection diary below.

Day	Date of Injection
Day 1	Date of first injection -
Day 2	
Day 3	
Day 4	
Day 5	
Day 6	
Day 7	
Day 8	
Day 9	
Day 10	
Day 11	
Day 12	
Day 13	
Day 14	
Day 15	
Day 16	
Day 17	
Day 18	
Day 19	
Day 20	
Day 21	
Day 22	
Day 23	
Day 24	
Day 25	
Day 26	
Day 27	
Day 28	Date of last injection -

Getting Started at Home



Supplemental Support

- **Website**

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

- **Video Demonstration**

Scan the QR code to access the tutorial video on **Preparing Your Injection Pen Before First Use** and **How to Administer Teriparatide Lupin**, or find it at <https://lupin.com.au/teriparatide-video>



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