

Package leaflet: Information for the user

Teriparatide 20 micrograms/80 microliters solution for injection in pre-filled pen

teriparatide

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Teriparatide is and what it is used for

Teriparatide contains the active substance teriparatide that is used to make the bones stronger, and to reduce the risk of fractures by stimulating bone formation.

Teriparatide is used to treat osteoporosis in adults. Osteoporosis is a disease that causes your bones to become thin and fragile. This disease is especially common in women after the menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

2. What you need to know before you use Teriparatide

Do not use Teriparatide

- if you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from high calcium levels (pre-existing hypercalcaemia)
- if you suffer from serious kidney problems
- if you have ever been diagnosed with bone cancer or other cancers that have spread (metastasised) to your bones
- if you have certain bone diseases. If you have a bone disease, tell your doctor
- if you have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget's disease of bone (disease with abnormal bone changes). If you are not sure, ask your doctor
- if you have had radiation therapy involving your bones - if you are pregnant or breast-feeding.

Warnings and precautions

Teriparatide may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using Teriparatide

- if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood
- if you suffer from kidney stones or have a history of kidney stones - if you suffer from kidney problems (moderate renal impairment).

Some patients get dizzy or get a fast heartbeat after the first few doses. For the first doses, inject Teriparatide where you can sit or lie down right away if you get dizzy. The recommended treatment time of 24 months should not be exceeded.

Teriparatide should not be used in growing adults.

Children and adolescents

Teriparatide should not be used in children and adolescents (less than 18 years).

Other medicines and Teriparatide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because occasionally they may interact (e.g. digoxin/digitalis, a medicine used to treat heart disease).

Pregnancy and breast-feeding

Do not use Teriparatide if you are pregnant, think you may be pregnant, or if you are breast-feeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of Teriparatide. If you become pregnant, Teriparatide should be discontinued. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Some patients may feel dizzy after injecting Teriparatide. If you feel dizzy you should not drive or use machines until you feel better.

Teriparatide contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to use Teriparatide

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

The recommended dose is 20 micrograms given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen. To help you remember to take your medicine, inject it at about the same time each day.

Inject Teriparatide each day for as long as your doctor prescribes it for you. The total duration of treatment with Teriparatide should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

Teriparatide can be injected at meal times.

Carefully read the ‘How to use the pre-filled pen’ section as provided at the end of this leaflet.

Injection needles are not included with the pen. Becton, Dickinson and Company pen needles can be used.

You should take your Teriparatide injection shortly after you take the pen out of the refrigerator as described in **PEN USER MANUAL** at the end of this leaflet. For instructions for use video, please scan the QR code included in the Pen User Manual or use the link: <https://www.pharmaqr.info/tpten>. Put the pen back into the refrigerator immediately after you have used it. Use a new injection needle of 31 Gauge, 5 mm length for each injection and dispose of it after each use. Never store your pen with the needle attached. Never share your Teriparatide pen with others.

Your doctor may advise you to take Teriparatide with calcium and vitamin D. Your doctor will tell you how much you should take each day.

Teriparatide can be given with or without food.

If you use more Teriparatide than you should

If, by mistake, you have used more Teriparatide than you should, contact your doctor or pharmacist. The effects of overdose that might be expected include nausea, vomiting, dizziness, and headache.

If you forget or cannot take Teriparatide at your usual time, take it as soon as possible on that day. Do not take a double dose to make up for a forgotten dose. Do not take more than one injection in the same day. Do not try to make up for a missed dose.

If you stop taking Teriparatide

If you are considering stopping Teriparatide treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Teriparatide.

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

4. Possible side effects

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

The most common side effects are pain in limb (frequency is very common, may affect more than 1 in 10 people) and feeling sick, headache and dizziness (frequency is common). If you become dizzy (light-headed) after your injection, you should sit or lie down until you feel better. If you do not feel better, you should call a doctor before you continue treatment. Cases of fainting have been reported in association with teriparatide use.

If you experience discomfort such as redness of the skin, pain, swelling, itching, bruising or minor bleeding around the area of the injection (frequency is common), this should clear up in a few days or weeks. Otherwise, tell your doctor as soon as possible.

Some patients may have experienced allergic reactions soon after injection, consisting of breathlessness, swelling of the face, rash and chest pain (frequency is rare). In rare cases, serious and potentially life-threatening allergic reactions including anaphylaxis can occur.

Other side effects include

Common (may affect up to 1 in 10 people)

- increase in blood cholesterol levels
- depression
- neuralgic pain in the leg
- feeling faint
- irregular heart beats
- breathlessness

- increased sweating
- muscle cramps
- loss of energy
- tiredness
- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- being sick(vomiting)
- a hernia of the tube that carries food to your stomach
- low haemoglobin or red blood cell count (anaemia)

Uncommon (may affect up to 1 in 100 people)

- increased heart rate
- abnormal heart sound
- shortness of breath
- haemorrhoids (piles)
- accidental loss or leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some patients have experienced severe back cramps or pain which lead to hospitalisation
- increase in blood calcium level
- increase in blood uric acid level
- increase in an enzyme called alkaline phosphatase.

Rare (may affect up to 1 in 1,000 people)

- reduced kidney function, including renal failure
- swelling, mainly in the hands, feet and legs.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Teriparatide

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 carton and pen after EXP. The expiry date refers to the last day of that month.

Teriparatide should be stored in a refrigerator (2°C to 8°C) at all times. You can use Teriparatide for up to 28 days after the first injection, as long as the pen is stored in a refrigerator (2°C to 8°C).

Do not freeze Teriparatide. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use Teriparatide if it is, or has been, frozen.

Each pen should be properly disposed of after 28 days, even if it is not completely empty.

Teriparatide contains a clear and colourless solution. Do not use Teriparatide if solid particles appear or if the solution is cloudy or coloured.

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 to protect the environment.

6. Contents of the pack and other information

What Teriparatide contains

- The active substance is teriparatide. Each dose of 80 microliters contains 20 micrograms of teriparatide.
Each pre-filled pen of 2.4 ml contains 600 micrograms of teriparatide (corresponding to 250 micrograms per ml).
- The other ingredients are glacial acetic acid (E260), anhydrous sodium acetate (E262), mannitol (E421), metacresol, and water for injections. In addition, hydrochloric acid (E507) and/or sodium hydroxide (E524) solution may have been added for pH adjustment.

What Teriparatide looks like and contents of the pack

Teriparatide is a clear and colourless solution. It is supplied in a cartridge contained in a disposable pre-filled pen. Each pen contains 2.4 ml of solution enough for 28 doses.

It is available in packs of 1 or 3 pens.

Not all package sizes may be marketed.

Marketing Authorisation Holder European Union

Sun Pharmaceutical Industries
Europe B.V.
Polarisavenue 87
2132JH Hoofddorp
The Netherlands

Great Britain

Sun Pharma UK Limited
6 - 9 The Square
Stockley Park
Uxbridge
UB11 1FW
United Kingdom

Manufacturers

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

Terapia S.A.
Str. Fabricii nr 124
Cluj-Napoca, Județul Cluj
Romania

This leaflet was last revised in May 2023.

Detailed information on this medicine is available on the European Medicines Agency website:

<http://www.ema.europa.eu>.

PEN USER MANUAL

Teriparatide 20 micrograms/80 microliters solution for injection in pre-filled pen

Instructions for use

Before you use your new pen, please read the section *Instructions for use* completely. Follow the directions carefully when using the pen. Also read the package leaflet provided.

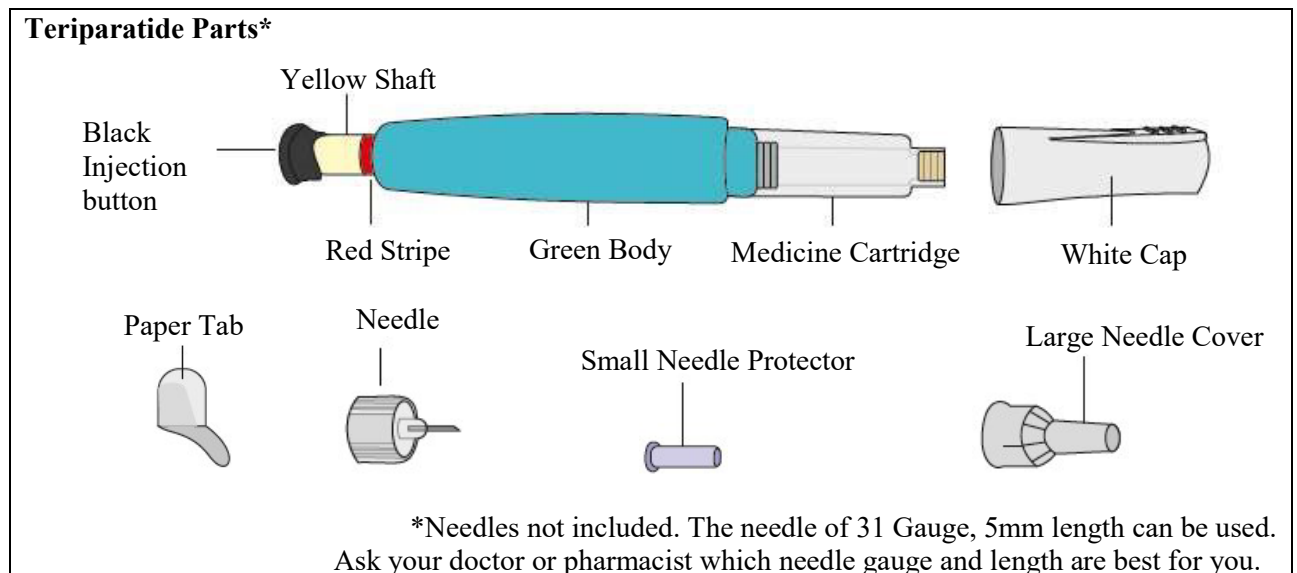
For instructions for use video, please scan the QR code or use the link:

<https://www.pharmaqr.info/tpten>.



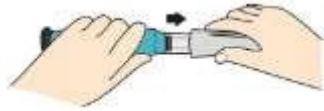
Do not share your pen or your needles as this may risk transmission of infectious agents.

Your pen contains 28 days of medicine.



Always wash your hands before every injection. Prepare the injection site as directed by your doctor or pharmacist.

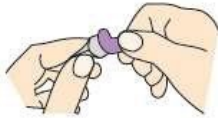
1



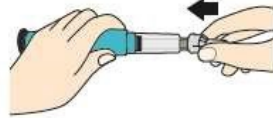
Pull off white cap

2

Attach new needle



Pull off paper tab

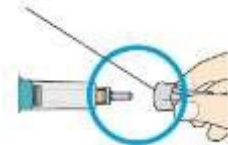


Push needle **straight onto medicine cartridge.**



Screw on needle until firmly attached.

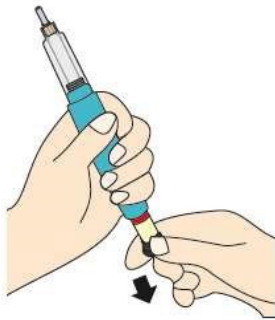
Large Needle Cover



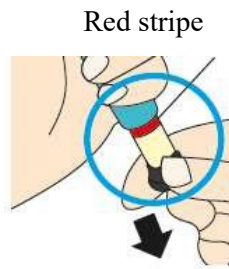
Pull off large needle cover and **save it.**

3

Set dose



Pull out black injection button **until it stops.**



Check to make sure red stripe shows.



Pull off small needle protector and throw away.

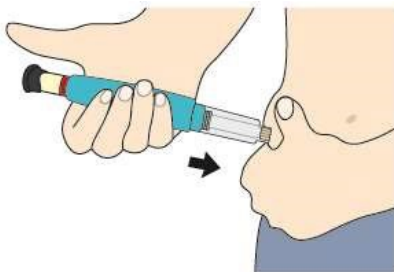
If you cannot pull out the black injection button see *Troubleshooting Problem E*.

Note: After removal of inner needle protector, you may see drop(s) of medicine coming out of the needle.

It is normal and will not affect your dose.

4

Inject dose



Gently hold a fold of skin from thigh or abdomen and insert needle straight into skin.



Push in black injection button until it stops.
Hold it in and **count to 5 s-l-o-w-l-y.**
Then pull the needle from skin.

IMPORTANT

5

Confirm dose



After completing the injection

Once the needle is removed from the skin, **check** to make sure the black injection button is all the way in. If the yellow shaft does not show, you have completed the injection steps correctly.

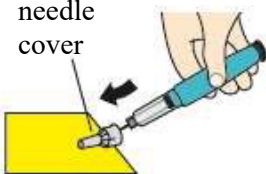


You should **NOT** see any of the yellow shaft. If you do and have already injected, do not inject yourself a second time on the same day. Instead, you **MUST reset Teriparatide** (See Troubleshooting Problem A).

6

Remove needle

Large
needle
cover



Put large needle
Cover on needle.



Unscrew the needle all the way
by giving the large needle
cover 3 to 5 complete turns.



Pull off needle and throw
away as directed by
your doctor or pharmacist.



Push white cap back on.
Place Teriparatide
in the refrigerator
immediately after use.

The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.



**Teriparatide 20 micrograms/80 microliters
solution for injection in pre-filled pen**

Troubleshooting

Problem

A. The yellow shaft is still showing after I push in the black injection button.

How do I reset my Teriparatide ?



Solution

To reset the Teriparatide, follow the steps below.

- 1) **If you have already injected, DO NOT inject yourself a second time on the same day.**
- 2) Remove the needle.
- 3) Attach a new needle, pull off the large needle cover and save it.
- 4) Pull out the black injection button until it stops. Check to make sure the red stripe shows.
- 5) Pull off the small needle protector and throw away.
- 6) Point the needle down into an empty container. Push in the black injection button until it stops. Hold it in and count to 5 s-l-o-w-l-y. You may see a small stream or drop of fluid. **When you have finished, the black injection button should be all the way in.**
- 7) If you still see the yellow shaft showing, please contact your doctor or pharmacist
- 8) Put the large needle cover on needle. Unscrew the needle all the way by giving the needle cover 3 to 5 complete turns. Pull off needle cover and throw away as directed by your doctor or pharmacist. Push the white cap back on, and place Teriparatide in the refrigerator.

You can prevent this problem by **always using a NEW needle for each injection, and by pushing the black injection button all the way in and counting to 5 s-l-o-w-l-y.**

B. How can I tell if my Teriparatide works?



The Teriparatide is designed to inject the full dose every time it is used according to the directions in the section *How to use*. The black injection button will be all the way in to show that the full dose has been injected from the Teriparatide.

Remember to use a new needle every time you inject to be sure your Teriparatide will work properly.

C. I see an air bubble in my Teriparatide.



A small air bubble will not affect your dose nor will it harm you. You can continue to take your dose as usual.

D. I cannot get the needle off.



- 1) Put the large needle cover on the needle.
- 2) Use the large needle cover to unscrew the needle.
- 3) Unscrew the needle all the way by giving the large needle cover 3 to 5 complete turns.
- 4) If you still cannot get the needle off, ask someone to help you.

E. What should I do if I cannot pull out the black injection button?



Change to a new Teriparatide to take your dose as directed by your doctor or pharmacist.

This indicates that you have now used all the medicine that can be injected accurately even though you may still see some medicine left in the cartridge.

Cleaning and Storage

Cleaning Your Teriparatide

- Wipe the outside of the Teriparatide with a damp cloth.
- Do not place the Teriparatide in water, or wash or clean it with any liquid.

Storing Your Teriparatide

- Refrigerate the Teriparatide immediately after every use. Read and follow the instructions in the *Information for the Patient leaflet* on how to store your pen.
- Do not store the Teriparatide with a needle attached as this may cause air bubbles to form in the cartridge.
- Store the Teriparatide with the white cap on.
- Never store the Teriparatide in the freezer.
- If the medicine has been frozen, throw the device away and use a new Teriparatide.
- If the Teriparatide has been left out of the refrigerator, do not throw the pen away. Place the pen back in the refrigerator and contact your doctor or pharmacist.

Disposal of Pen Needles and Device

Disposal of Pen Needles and Teriparatide Device

- Before disposing of the Teriparatide device, be sure to remove the pen needle.
- Put used needles in a sharps container or a hard plastic container with a secure lid. Do not throw needles directly into your household waste.
- Do not recycle the filled sharps container.
- Ask your healthcare professional about options to dispose of the pen and the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.
- Dispose of the device 28 days after first use.

Other Important Notes

- The Teriparatide contains 28 days of medicine.
- Do not transfer the medicine into a syringe.
- Write down your first injection date on a calendar.
- Read and follow the instructions in the *Information for the Patient leaflet* for using the medicine.
- Check the Teriparatide label to make sure you have the correct medicine, and that it has not expired.
- Contact your doctor or pharmacist if you notice any of the following: -
 - The Teriparatide appears damaged
 - The solution is NOT clear, colourless and free of particles
- Use a new needle for each injection.
- During injection, you may hear one or more clicks – this is a normal device operation.
- The Teriparatide is not recommended for use by the blind or visually impaired persons without the assistance of a person trained in the proper use of the device.
- Keep the Teriparatide out of the sight and reach of children.