

## **Package leaflet: Information for the user**

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

#### **1. What Teriparatide SUN is and what it is used for**

Teriparatide SUN 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 SUN 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 SUN**

##### **Do not use Teriparatide SUN**

- 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 SUN 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 SUN

- 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 SUN 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 SUN should not be used in growing adults.

### **Children and adolescents**

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

### **Other medicines and Teriparatide SUN**

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 SUN 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 SUN. If you become pregnant, Teriparatide SUN 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 SUN. If you feel dizzy you should not drive or use machines until you feel better.

### **Teriparatide SUN 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 SUN**

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

Teriparatide SUN 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 SUN 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 SUN pen with others.

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

Teriparatide SUN can be given with or without food.

#### **If you use more Teriparatide SUN than you should**

If, by mistake, you have used more Teriparatide SUN 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 SUN 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 SUN**

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

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 SUN 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](http://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 SUN**

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 SUN might be stored before the first opening at 25°C for 24 hours.

Teriparatide SUN should be stored in a refrigerator (2°C to 8°C) at all times. You can use Teriparatide SUN 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 SUN. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use Teriparatide SUN 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 SUN contains a clear and colourless solution. Do not use Teriparatide SUN 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 SUN 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 SUN looks like and contents of the pack**

Teriparatide SUN 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**

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 January 2025.**

## **PEN USER MANUAL**

Teriparatide SUN 20 micrograms/80 microliters solution for injection in pre-filled pen  
V004

## **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.

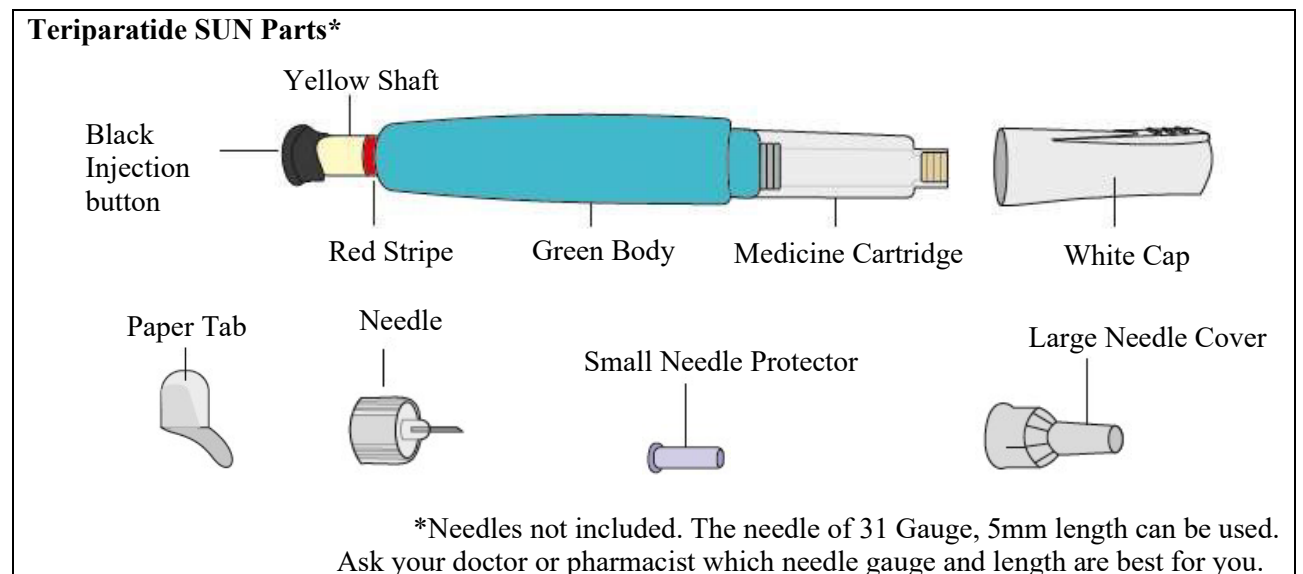
For instructions for use video, please scan the QR code or use the link:

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



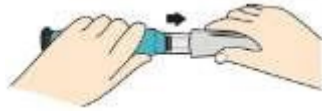
Do not share your pen or your needles as this may risk transmission of infectious agents.

**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.**

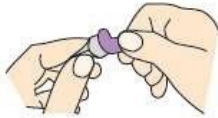
1



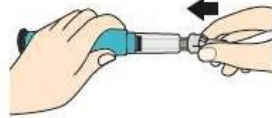
**Pull off white cap**

2

**Attach new needle**



**Pull off paper tab**

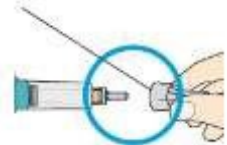


**Push needle *straight* onto medicine cartridge.**



**Screw on needle until firmly attached.**

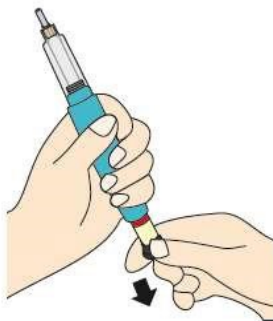
Large Needle Cover



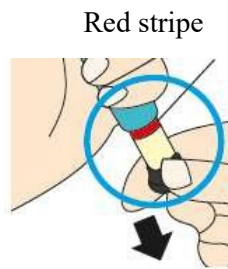
**Pull off large needle cover and *save it*.**

3

**Set dose**

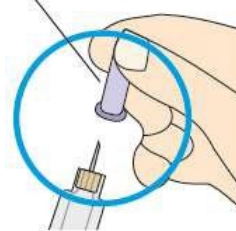


**Pull out black injection button *until it stops*.**



**Check to make sure red stripe shows.**

Small needle protector



**Pull off small needle protector and throw away.**

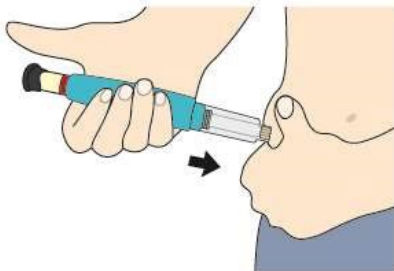
If you cannot pull out the black injection button see *Troubleshooting Problem E*.

**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.

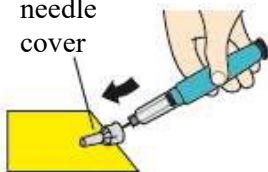


You should **NOT** see any of the yellow shaft. If you do and have already injected, do not inject yourself a second time on the same day. Instead, you **MUST** reset Teriparatide SUN (See Troubleshooting Problem A).

6

### Remove needle

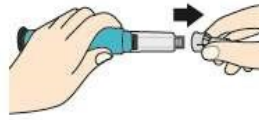
Large  
needle  
cover



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 SUN  
in the refrigerator  
immediately after use.

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



**Teriparatide SUN 20 micrograms/80 microliter  
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 SUN ?**



### Solution

To reset the Teriparatide SUN, 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 SUN 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 SUN works?**



The Teriparatide SUN 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 SUN.

**C. I see an air bubble in my Teriparatide SUN.**



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

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 SUN 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 SUN**

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

#### **Storing Your Teriparatide SUN**

- Refrigerate the Teriparatide SUN 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 SUN with a needle attached as this may cause air bubbles to form in the cartridge.
- Store the Teriparatide SUN with the white cap on.
- Never store the Teriparatide SUN in the freezer.
- If the medicine has been frozen, throw the device away and use a new Teriparatide SUN.
- If the Teriparatide SUN 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 SUN Device**

- Before disposing of the Teriparatide SUN 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 SUN 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 SUN 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 SUN 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 SUN 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 SUN out of the sight and reach of children.