

Teriparatide 20 µg/80 µl, solution for injection in pre-filled pen
Module 1.3.1.

PACKAGE LEAFLET

Package leaflet: Information for the user
[INVENTED NAME] 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 [INVENTED NAME] is and what it is used for
2. What you need to know before you use [INVENTED NAME]
3. How to use [INVENTED NAME]
4. Possible side effects
5. How to store [INVENTED NAME]
6. Content of the pack and other information

1. What is [INVENTED NAME] and what it is used for

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

[INVENTED NAME] 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 [INVENTED NAME]

Do not use [INVENTED NAME]

- 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.

Warning and precautions

[INVENTED NAME] may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using [INVENTED NAME]:

- 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 [INVENTED NAME] where you can sit or lie down right away if you get dizzy. The recommended treatment time of 24 months should not be exceeded.

[INVENTED NAME] should not be used in growing adults.

Children and adolescents

[INVENTED NAME] should not be used in children and adolescents (less than 18 years).

Other medicines and [INVENTED NAME]

Please 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 [INVENTED NAME] if you are pregnant or breast-feeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of [INVENTED NAME]. If you become pregnant, [INVENTED NAME] 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 [INVENTED NAME]. If you feel dizzy you should not drive or use machines until you feel better.

Important information about some of the ingredients of [INVENTED NAME]

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

3. How to use [INVENTED NAME]

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 (corresponding to 80 microliters) 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.

Before you use your pen the first time, it has to be prepared. Please refer also to the attached user manual.

Inject [INVENTED NAME] each day for as long as your doctor prescribes it for you. The total duration of treatment with [INVENTED NAME] should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime. [INVENTED NAME] can be injected at meal times.

Read the user manual, which is included in the carton for instructions on how to use the [INVENTED NAME] pen.

Injection needles are not included with the pen. For example, Becton, Dickinson and Company pen needles 29 to 31 gauge (diameter 0.25-0.33 mm) and 12.7, 8 or 5 mm length can be used.

You should take your [INVENTED NAME] injection shortly after you take the pen out of the refrigerator as described in the user manual. Put the pen back into the refrigerator immediately after you have used it. Use a new injection needle for each injection and dispose of it after each use. Never store your pen with the needle attached. Never share your [INVENTED NAME] pen with others.

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

[INVENTED NAME] can be given with or without food.

If you use more [INVENTED NAME] than you should

If, by mistake, you have used more [INVENTED NAME] 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 [INVENTED NAME] 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 [INVENTED NAME]

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

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 [INVENTED NAME] 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
- spinning sensations
- 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [INVENTED NAME]

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.

[INVENTED NAME] should be stored in a refrigerator (2°C to 8°C) at all times. You can use [INVENTED NAME] 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 [INVENTED NAME]. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use [INVENTED NAME] if it is, or has been, frozen.

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

[INVENTED NAME] contains a clear and colorless solution. Do not use [INVENTED NAME] if solid particles appear or if the solution is cloudy or colored.

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 [INVENTED NAME] contains

- The active substance is teriparatide. Each ml of the solution for injection contains 250 micrograms of teriparatide.
- The other ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, and water for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added for pH adjustment.

What [INVENTED NAME] looks like and contents of the pack

[INVENTED NAME] is a colorless and clear solution. It is supplied in a cartridge contained in a pre-filled disposable pen. Each pen contains 2.4 ml of solution enough for 28 doses. The pens are available in cartons containing 1 or 3 pens. Not all pack sizes may be available.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

This medicinal product is authorised in the Member States of the EEA under the following names:

This leaflet was last revised in

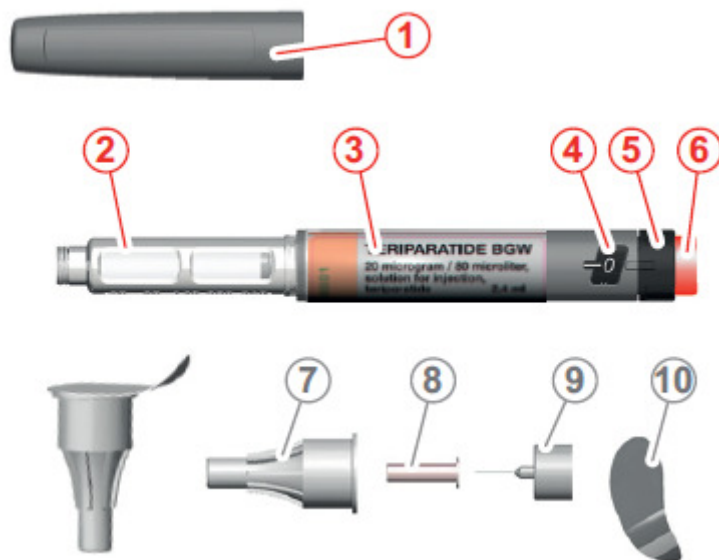
PEN USER MANUAL

User Manual Instructions for use

Overview

[INVENTED NAME] is a medicine supplied in a pen. The pen contains medicine for a once daily injection on 28 consecutive days.

Use a new needle for each injection. Needles are not supplied with the pen.



1. pen cap
2. cartridge with medicine
3. label
4. dose window
5. dose knob
6. dose activator
7. needle cap
8. needle protection
9. needle
10. seal foil

For your safety

Important information

- Read the instructions for use completely. Follow all directions carefully.
- Read the package leaflet provided with your pen.
- In case of questions, contact your physician, pharmacist or caregiver.

Prevention of infectious diseases

- Do not share your pen as this may risk transmission of infectious diseases.
- Use a new sterile needle for each injection. Used needles pose a risk of transmission of infectious diseases.

Use of pen

- Check the pen label when taking the pen out of the refrigerator. Ensure that you use the right medicine.
- Check the expiry date, do not use the pen in case the expiry date is exceeded.
- Check the medicine: it must be clear, colourless and free of particles.
- Do not use the pen for more than 28 injections. Note the first day of injection in the injection diary on the back side of these instructions for use. Calculate the date for 28th injection by using a calendar and also note this date in the injection diary.
- The pen is not recommended for use by the blind or visually impaired without help from a supporting person.
- Do not transfer the medicine to a syringe. [INVENTED NAME] has to be administered using this pen only.

Preparation for injection

- Wash your hands before every injection.
- Prepare the injection site as directed by your physician, pharmacist or caregiver.

Storage

- Keep pen in the refrigerator, preferably in a door compartment.
- Keep pen and needles out of the reach of children.

Troubleshooting

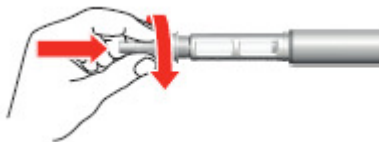
- If you encounter an issue with the injection, do not give a second injection the same day.
- Read the section "What to do if..." in these instructions for use.
- Do not use the pen if it is damaged.
- Only use the pen if the medicine is clear, colourless and free of particles.
- If you cannot solve the issue by yourself or if you are uncertain, contact your physician, pharmacist of caregiver.

A - Attaching the needle

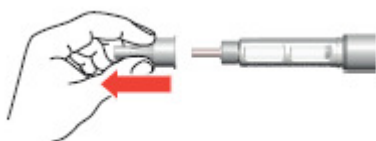
- 1) Remove pen cap.
- 2) Take a new needle and remove the seal foil from the needle cap.



- 3) Attach needle cap to the pen. Screw needle cap clockwise until hard stop.



- 4) Remove needle cap from the needle and keep the needle cap.



If you have not used your pen before, you have to prepare it for the first injection as described in section **B**.

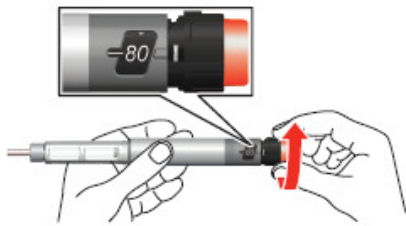
If you have used your pen before, it is ready for injection after the needle is attached. Proceed as described in section **C**.

B - Preparing the pen for the first injection

Before first injection, you have to prepare your pen. This step is not needed for the second and any following injections.

A new needle must be attached as described in section **A**, before taking the next steps.

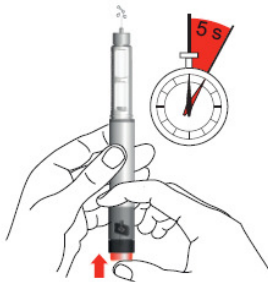
- 1) Turn the dose knob to the hard stop. Make sure the figure "80" is fully visible and centered in the dose window with the white mark aligned in the window notch.



- 2) Remove needle protection from the needle and dispose it.



- 3) Hold pen with needle up. Push the dose activator to the hard stop and hold for 5 seconds. Collect the expelled liquid with a cloth.



After preparation of pen, remove needle as described in section **D**.

Note the current date and the date of 28th injection in the injection diary on the back side of these instructions for use.

Now your pen is ready for the first injection.

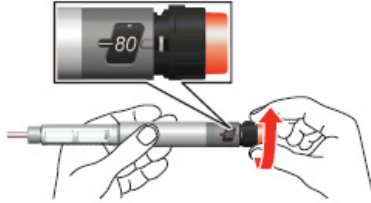
C - Injecting medicine

If you use your pen the first time, you have to prepare it as described in section **B**.

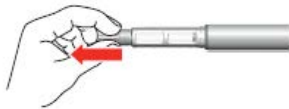
Before taking the following steps a new needle must be attached to the pen as described in section **A**. Use a new needle for every injection because a new needle is sharp and allows an almost pain-free injection. A used needle poses a risk of being clogged or contaminated.

You must have been prepared the injection site as directed by your physician, pharmacist or caregiver.

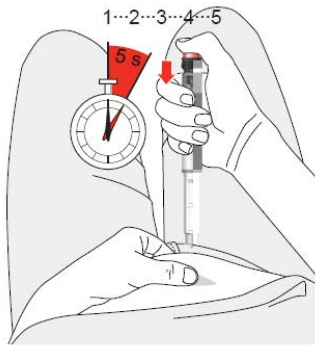
- 1) Turn the dose knob to the hard stop. Make sure the figure "80" is fully visible and centered in the dose window with the white mark aligned in the window notch.



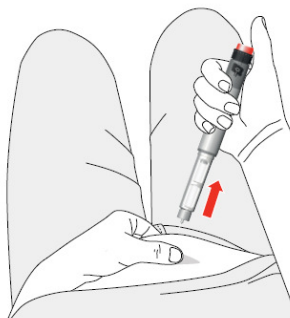
- 2) Remove needle protection from the needle and dispose it.



- 3) Gently hold a fold of skin from thigh or abdomen.
- 4) Insert the needle at a 90 degree angle at the cleaned injection site. Push the dose activator to the hard stop and hold for 5 seconds. Count up slowly to 5.



- 5) Pull out the needle from the skin.



- 6) Confirm dose. Make sure the figure "0" is fully visible and centered 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.

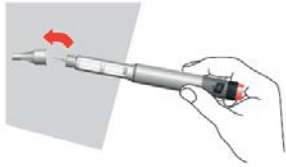


After injection, remove needle from pen, as described in section **D**.

D- Removing needle

Always remove needle immediately after use of pen.

- 1) Carefully push needle into the needle cap. Do not touch the needle or needle cap.



- 2) Unscrew needle by turning the needle cap counter clockwise and pull needle from pen.



- 3) Dispose needle with needle cap in a puncture safe container which can be obtained at your pharmacy or from your caregiver.
- 4) Re-attach pen cap to pen.

E – Storing the pen

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

Only take pen out of the refrigerator for use. Store pen in the refrigerator, preferably in a door compartment. Don't store pen next to the back wall of refrigerator or in the freezer. The medicine becomes unusable if frozen.

In case your pen was not stored in the refrigerator for a longer time, it should not be thrown away. Put pen back in the refrigerator and contact your physician, pharmacist or caregiver.

F – Disposing pen

The pen must be disposed at the day of the last injection (see injection diary). Dispose pen even in case of remaining medicine in the cartridge.

Dispose pen as directed by your physician or pharmacist.

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

What to do if....

Air bubble in cartridge: You can use your pen without any concern.

While preparing pen for first use no medicine is expelled: Perform steps as described in section **B** again.

The dose activator is blocked or you have the impression you have not injected the full dose: Do not give a second injection the same day. Proceed with your regular injection the next day. Make sure you turn the dose knob to the hard stop and the figure "80" is fully visible in the dose window.

Injection diary	
Date of first injection	day 1
<u>Manufacturer</u>	
Date of last injection	day 28

This user manual was last updated on