PACKAGE LEAFLET

Package leaflet: Information for the user

Teriparatide Cipla 20 micrograms/80 microlitres 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 Cipla is and what it is used for
2. What you need to know before you use Teriparatide Cipla
3. How to use Teriparatide Cipla
4. Possible side effects
5. How to store Teriparatide Cipla
6. Contents of the pack and other information

1. What Teriparatide Cipla is and what it is used for

Teriparatide Cipla 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 Cipla 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 Cipla

Do not use Teriparatide Cipla

- 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 Cipla 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 Cipla:
- 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 Cipla 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 Cipla should not be used in growing adults.

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

Other medicines and Teriparatide Cipla
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 Teriparatide Cipla 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 Teriparatide Cipla. If you become pregnant, Teriparatide Cipla 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 Cipla. If you feel dizzy you should not drive or use machines until you feel better.

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

This medicine also contains metacresol, which may cause allergic reactions.

3. How to use Teriparatide Cipla

Always use this medicine exactly as your doctor has told you. 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 Cipla each day for as long as your doctor prescribes it for you. The total duration of treatment with Teriparatide Cipla should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

Teriparatide Cipla can be injected at meal times.

Read the user manual booklet, which is included in the carton for instructions on how to use the Teriparatide Cipla pen.

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

You should take your Teriparatide Cipla 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 Teriparatide Cipla pen with others.

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

Teriparatide Cipla can be given with or without food.

If you use more Teriparatide Cipla than you should
If, by mistake, you have used more Teriparatide Cipla 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 Cipla
If you forget or cannot take Teriparatide Cipla 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 Cipla
If you are considering stopping Teriparatide Cipla treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Teriparatide Cipla.

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 national reporting system
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Teriparatide Cipla

- 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 pre-filled pen label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C). You can use Teriparatide Cipla for up to 28 days after the first injection, as long as the pen is stored in a refrigerator (2°C to 8°C).

- Recap the pre-filled pen when not in use to protect the cartridge from physical damage and light.
- When using Teriparatide Cipla, minimize the time out of the refrigerator, deliver the dose immediately following removal from the refrigerator.
- Do not freeze Teriparatide Cipla. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing.
- Each pen should be properly disposed of after 28 days, even if it is not completely empty.
- Do not use Teriparatide Cipla 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 protect the environment.

6. Contents of the pack and other information

What Teriparatide Cipla contains
- The active substance is teriparatide (as acetate salt). Each dose of 80 microlitres contains 20 micrograms of teriparatide. One pre-filed pen of 2.4 mL contains 600 micrograms of teriparatide (corresponding to 250 micrograms per mL).
- The other ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, and water for injections.

What Teriparatide Cipla looks like and contents of the pack
Teriparatide Cipla is a colorless and clear solution.

Teriparatide Cipla is a 2.4 mL solution in glass cartridge with bromobutyl rubber plunger, polyisoprene/bromobutyl rubber/aluminium disc seal assembled in a pre-filled pen.

Teriparatide Cipla is available in pack sizes of 1 or 3 pre-filled pens. Each pre-filled pen contains 28 daily doses of 20 micrograms teriparatide (equivalent to 80 microlitres of drug product).

Not all pack sizes may be available.

Marketing Authorisation Holder
Cipla Europe NV
De Keyserlei 60C, Bus-1301, 2018,
Antwerp, Belgium

Manufacturer
Cipla Europe NV
De Keyserlei 60C, Bus-1301, 2018,
Antwerp, Belgium

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the medicine
Germany	Teriparatid Cipla 20 Mikrogramm/80 Mikroliter Injektionslösung in einem Fertigpen
Spain	Teriparatida Cipla 20 microgramos/80 microlitros solución inyectable en pluma precargada EFG
Norway	Teriparatide Cipla
France	Tériparatide Cipla 20 microgrammes/ 80 microlitres, solution injectable en stylo prérempli
Italy	Teriparatide Cipla
Austria	Teriparatid Cipla 20 Mikrogramm/80 Mikroliter Injektionslösung in einem Fertigpen
Ireland	Teriparatide Cipla 20 micrograms /80 microlitres solution for injection in pre-filled pen
Netherlands	Teriparatide Cipla 20 microgram/ 80 microliter,

	oplossing voor injectie in voorgevulde pen

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PEN USER MANUAL

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

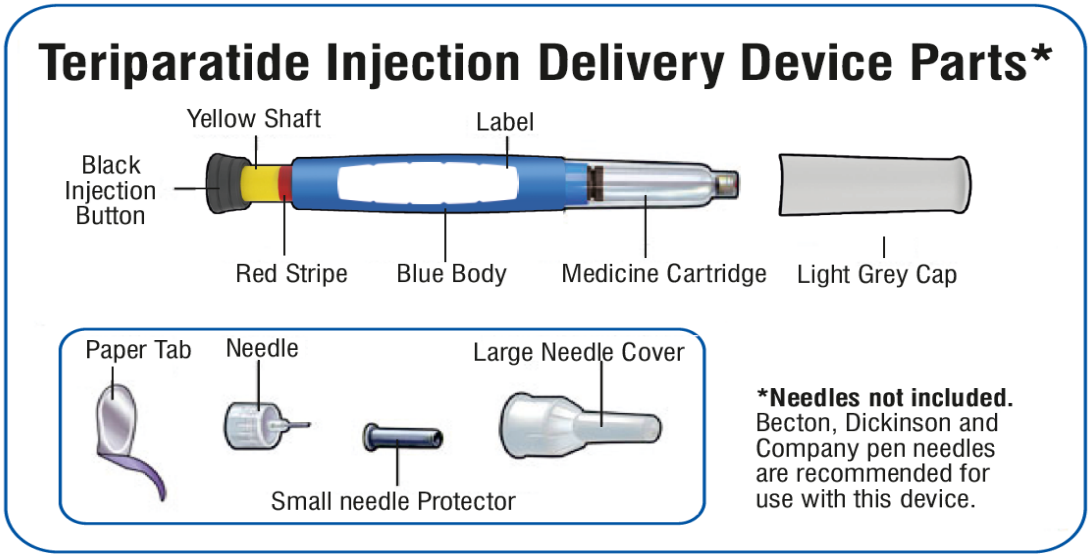
Important: First read the Package leaflet that comes inside your Teriparatide Cipla carton.

Instructions for use
Before you use your new Teriparatide Cipla pre-filled pen, please read the entire front and back section of *Instructions for use* completely. Follow the directions carefully when using the pre-filled pen.

Do not share your pre-filled pen or needles because infection or disease can be spread from one person to another.

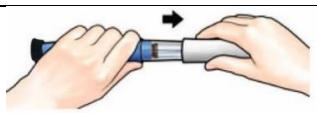
The Teriparatide Cipla pre-filled pen contains 28 days of medicine. Throw away the Teriparatide Cipla pen after 28 days, even if it is not completely empty. Do not inject more than one dose of Teriparatide Cipla in the same day.

Do not transfer Teriparatide Cipla to a syringe.



Wash your hands before every injection. Prepare the injection site as your healthcare provider instructed.

1. Pull off light grey cap



Check the Teriparatide Cipla pre-filled pen label to make sure you have the right medicine and that it has not expired

Do not use if the Teriparatide Cipla pre-filled pen looks damaged, if the medicine in the cartridge is not clear and colorless, or if it has particles in it.

2. Attached new needle



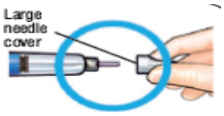
Pull off paper tab.



Push needle **straight** onto medicine cartridge.

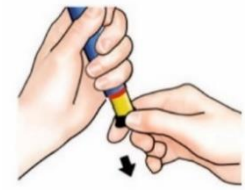


Screw on needle clockwise until firmly attached.



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

3. Set dose



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

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

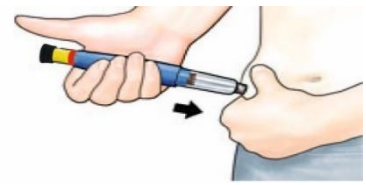


Check to make sure red stripe shows.



Pull off small needle protector and throw away.

4. Inject dose



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



Push in black injection button until it stops. Hold it in and **count to 5 slowly.**
You must wait until the count of 5 to make sure you receive the correct dose.
Then pull the needle from skin.

IMPORTANT

5. Confirm dose

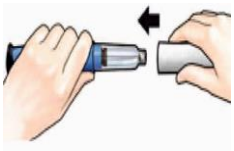


After completing the injection:
Once the needle is removed from the skin, take your thumb off the black injection button.
Check to make sure the black injection button is all the way in.



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

	If the yellow shaft does not show, you have finished the injection steps the right way.	**Cipla** pre-filled pen (see Troubleshooting Problem A).

6. Remove needle				
	Put large needle cover on needle. Do not try to put the needle cover back on with your hands.	Unscrew the covered needle all the way by giving the large needle cover 3 to 5 counter-clockwise turns.	Pull off needle and throw away in a puncture-resistant container.	Push light grey cap back on. Right after use, place Teriparatide Cipla pre-filled pen in the refrigerator
For more information, or if you have any questions, turn to the back of this page.				



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

TROUBLESHOOTING	
PROBLEM	**SOLUTION**
A. The yellow shaft is still showing after I push in the black injection button. How do I reset my Teriparatide Cipla pre-filled pen? 	To reset the Teriparatide Cipla pre-filled pen, 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 **slowly count to five**. 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, contact Cipla Ltd. (see Contact Information below) or your healthcare provider. 8) Put the large needle cover on needle. Unscrew the needle all the way by giving the needle cover 3 to 5 counter-clockwise turns. Pull off the covered needle and throw away

	as instructed by your healthcare provider. Push the light grey cap back on, and put your Teriparatide Cipla pre-filled pen 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 slowly counting to five.**
B. How can I tell if my Teriparatide Cipla pre-filled pen works?	As the full injection dose should be administered every time, the black injection button should be all the way in to show that the full dose of medicine has been injected from the Teriparatide Cipla pen. Use a new needle every time you inject to be sure your Teriparatide Cipla pre-filled pen will work properly.
C. I see an air bubble in my Teriparatide Cipla.	A small air bubble will not affect your dose and it will not 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 counter-clockwise turns. 4) If you still cannot get the needle off, ask someone to help you.
E. What should I do if I have difficulty pulling out the black injection button?	**Change to a new Teriparatide Cipla pre-filled pen to take your dose as instructed by your healthcare provider.** When the black injection button becomes hard to pull out, this means there is not enough medicine in your Teriparatide Cipla pre-filled pen for another dose. You may still see some medicine left in the cartridge.

CLEANING AND STORAGE

Cleaning Your Teriparatide Cipla pre-filled pen

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

Storing Your Teriparatide Cipla pre-filled pen

- After each use, refrigerate the Teriparatide Cipla pre-filled pen right away. Read and follow the instructions in the *Information for the user leaflet* on how to store Teriparatide Cipla.
- Do not store the Teriparatide Cipla pen with a needle attached. Doing this may cause air bubbles to form in the medicine cartridge.
- Store the Teriparatide Cipla pre-filled pen with the light grey cap on.
- Do not freeze Teriparatide Cipla. If the Teriparatide Cipla pre-filled pen has been frozen, throw the device away and use a new Teriparatide Cipla pre-filled pen.
- If the Teriparatide Cipla pre-filled pen has been left out of the refrigerator, do not throw the pre-filled pen away. Place the pre-filled pen back in the refrigerator and contact your doctor or pharmacist.

DISPOSAL OF PEN NEEDLES AND PRE-FILLED PEN

Disposal of Pen Needles and the Teriparatide Cipla pre-filled pen

- Before throwing away the Teriparatide Cipla pre-filled pen, be sure to remove the pen needle.
- Throw away your Teriparatide Cipla pre-filled pen and used needles as instructed by your healthcare provider, local or state laws, or institutional policies.

OTHER IMPORTANT NOTES

- The Teriparatide Cipla pre-filled pen 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 product.
- Check the Teriparatide Cipla pre-filled pen 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 Cipla pre-filled pen 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 Cipla pre-filled pen 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 Cipla pre-filled pen out of the sight and reach of children.

Dispose of the Teriparatide Cipla pre-filled pen 28 days after first use	**1st use date** _____/_____/_____ **Throw away after** _____/_____/_____

Contact Information

If you have questions or need help with your Teriparatide Cipla pre-filled pen, contact Cipla Ltd or your healthcare provider.

This user manual was last revised in {MM/YYYY}
To be completed nationally>