

Package leaflet: Information for the user

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

### 1. What Teriparatide Biotech is and what it is used for

Teriparatide Biotech 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 Biotech 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 Biotech

**Do not use Teriparatide Biotech**

- 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**

Teriparatide Biotech 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 Biotech:

- 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 Biotech 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 Biotech should not be used in growing adults.

**Children and adolescents**

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

### 3. How to use Teriparatide Biotech

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

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

You should take your Teriparatide Biotech 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 Biotech pen with others.

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

Teriparatide Biotech can be given with or without food.

### 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 the limbs (frequency is very common: may affect more than 1 in 10 people) and feeling sick, headache and dizziness (frequency is common). If you become

### Other medicines and Teriparatide Biotech

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

### Important information about some of the ingredients of Teriparatide Biotech

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

<p>TECHNICAL COLOUR NON PRINTABLE</p> <p>Keyline Info guide</p>	<p>Approved by: <b>Biotech Pharma Limited</b></p> <p>Technical approval by: <b>Manufacturer</b></p>	
---	---	--

	<p>JOB NUMBER <b>BP0009/N</b></p>	<p>JOB CATEGORY <b>NEW</b></p>	<p>VERSION <b>03</b></p>	<p>CUSTOMER: <b>BIOTECH PHARMA LIMITED</b></p> <p>PRODUCT: <b>Teriparatide Biotech 20mcg/80µL solution - PIL</b></p>
	<p>DIMENSIONS (mm) <b>280x270</b></p>	<p>COLOURS: <b>1</b></p>	<p><b>Black</b></p>	

Formatting Criteria	Teriparatide Biotech 20mcg/80µL solution
Single Page Dimensions	280 (W) x 270 (H)
Number of Pages	2
Font Style	Frutiger LT Std
Font Size – Headings	15.5 pt
Font Size – Sub headings	11 pt
Font Size – Body text	9 pt
Margins	Top/Bottom/Right/Left: 10 mm
Line-spacing	3.8 mm
Pictograms	NA

TRACKING: 22.06.2025/ 26.06.2025/ 16.07.2025

<p>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.</p> <p>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.</p> <p>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.</p> <p>Other side effects include:</p> <p><b>Common: may affect up to 1 in 10 people</b></p> <ul style="list-style-type: none"> <li>• increase in blood cholesterol levels</li> <li>• depression</li> <li>• neuralgic pain in the leg</li> <li>• feeling faint</li> <li>• irregular heart beats</li> <li>• breathlessness</li> <li>• increased sweating</li> <li>• muscle cramps</li> <li>• loss of energy</li> <li>• tiredness</li> <li>• chest pain</li> <li>• low blood pressure</li> <li>• heartburn (painful or burning sensation just below the breast bone)</li> <li>• being sick (vomiting)</li> <li>• a hernia of the tube that carries food to your stomach</li> <li>• low haemoglobin or red blood cell count (anaemia)</li> </ul> <p><b>Uncommon: may affect up to 1 in 100 people</b></p> <ul style="list-style-type: none"> <li>• increased heart rate</li> <li>• abnormal heart sound</li> <li>• shortness of breath</li> <li>• haemorrhoids (piles)</li> <li>• accidental loss or leakage of urine</li> <li>• increased need to pass water</li> <li>• weight increase</li> <li>• kidney stones</li> <li>• pain in the muscles and pain in the joints. Some patients have experienced severe back cramps or pain, which led to hospitalisation.</li> <li>• increase in blood calcium level</li> <li>• increase in blood uric acid level</li> </ul>	<ul style="list-style-type: none"> <li>• increase in an enzyme called alkaline phosphatase.</li> </ul> <p><b>Rare: may affect up to 1 in 1,000 people</b></p> <ul style="list-style-type: none"> <li>• reduced kidney function, including renal failure</li> <li>• swelling, mainly in the hands, feet and legs.</li> </ul> <p><b>Reporting of side effects</b> 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 <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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.</p> <p><b>5. How to store Teriparatide Biotech</b></p> <p>Keep this medicine out of the sight and reach of children.</p> <p>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.</p> <p>Teriparatide Biotech should be stored in a refrigerator (2°C to 8°C) at all times. You can use the pen for up to 28 days after the first injection, as long as the pen is stored in a refrigerator (2°C to 8°C).</p> <p>Do not freeze Teriparatide Biotech. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use the pen if it is, or has been, frozen.</p> <p>Each pen should be properly disposed of after 28 days, even if it is not completely empty.</p> <p>Teriparatide Biotech contains a clear and colorless solution. Do not use Teriparatide Biotech if solid particles appear or if the solution is cloudy or coloured.</p> <p>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.</p>	<p><b>6. Contents of the pack and other information</b></p> <p><b>What Teriparatide Biotech contains</b></p> <ul style="list-style-type: none"> <li>• The active substance is teriparatide. Each ml of the solution for injection contains 250 micrograms of teriparatide.</li> <li>• The other ingredients are glacial acetic acid, sodium acetate, mannitol, metacresol, and water for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added for pH adjustment.</li> </ul> <p><b>What Teriparatide Biotech looks like and contents of the pack</b> Teriparatide Biotech 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.</p> <p><b>Marketing Authorisation Holder</b> Biotech Pharma Limited Quantum House, Hobson, Newcastle Upon Tyne, NE16 6EA, United Kingdom</p> <p><b>Manufacturer</b> GP-PHARM, S.A. Polígono Industrial Els Vinyets-El's Fogars, Sector 2, Carretera Comarcal C-244, Km 22 08777 Sant Quintí de Mediona Spain</p> <p><b>This leaflet was last revised in</b> 06/2025</p>	
---	--	---	--

Approved by: <b>Biotech Pharma Limited</b>	Technical approval by: <b>Manufacturer</b>

TECHNICAL COLOUR  
NON PRINTABLE



	JOB NUMBER <b>BP0009/N</b>	JOB CATEGORY <b>NEW</b>	VERSION <b>03</b>	CUSTOMER: <b>BIOTECH PHARMA LIMITED</b>
	DIMENSIONS (mm) <b>280x270</b>	COLOURS: <b>1</b>	<b>Black</b>	PRODUCT: <b>Teriparatide Biotech 20mcg/80µL solution - PIL</b>
TRACKING: <b>22.06.2025/ 26.06.2025/ 16.07.2025</b>				

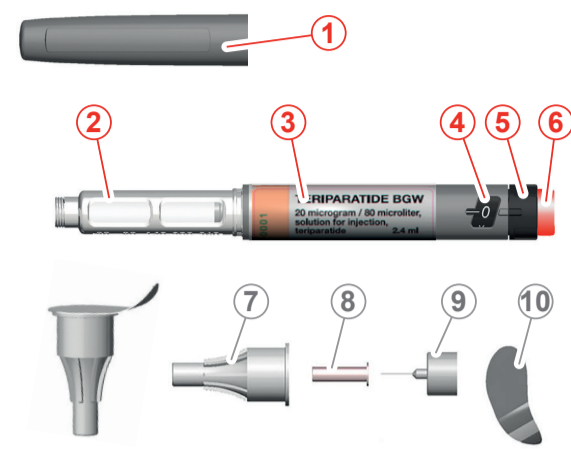
Formatting Criteria	Teriparatide Biotech 20mcg/80µL solution
Single Page Dimensions	280 (W) x 270 (H)
Number of Pages	2
Font Style	Frutiger LT Std
Font Size – Headings	15.5 pt
Font Size – Sub headings	11 pt
Font Size – Body text	9 pt
Margins	Top/Bottom/Right/Left: 10 mm
Line-spacing	3.8 mm
Pictograms	NA

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

## Instructions for use

Before you use your new pen, please read these instructions carefully. Follow the directions carefully when using the pen. Also read the package leaflet provided. Your pen contains 28 days of medicine.

Teriparatide Biotech Parts\*



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

\* Needles are not included. Becton, Dickinson and Company pen needles can be used. Ask your doctor or pharmacist which needle gauge and length are best for you.

## For your safety

### Prevention of infectious diseases

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

### Use of the 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 if it has expired.
- Check the medicine. It must be clear, colourless and free of particles.
- Do not transfer the medicine to a syringe. It must be administered using this pen only.
- Do not use the pen for more than 28 injections. Note the first day of injection in the Injection Diary on the back of these Instructions for Use. Calculate the date for the 28th injection by using a calendar and make a note of this date in the Injection Diary.
- The pen is not recommended for use by the blind or visually impaired without help from a person who is trained in the proper use of the device.

### Storage

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

### Troubleshooting

- If you have a problem with the injection, do not give a second injection on 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 problem by yourself or if you are uncertain, contact your doctor, pharmacist, nurse or carer.

## Preparing the pen before the first injection

Follow these instructions every time you prepare a new pen before the first injection.

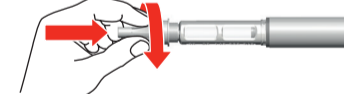
**You only have to perform this step once. You do NOT need to repeat this step for the second, third or any further injections.**

### Attaching the needle

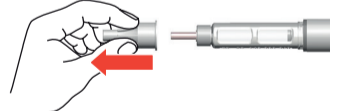
1. Remove the pen cap.
2. Take a new needle and remove the seal foil from the large outer cap.



3. Attach the needle with the large outer cap to the pen. Screw the large outer cap clockwise as far as it will go.

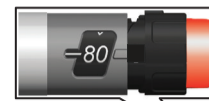


4. Remove the large outer cap from the needle and save it.

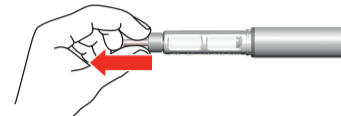


### Dialling the Dose

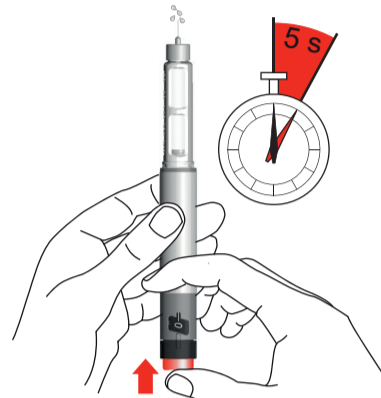
5. Turn the dose knob clockwise to the hard stop (until it cannot be rotated any further). Make sure the figure "80" is fully visible and centred in the dose window. The white mark and the window notch should be aligned.



6. Remove the small inner cap from the needle and throw away.



7. Hold the pen with the needle up. Push the dose activator as far as it will go (to the hard stop) and hold for 5 seconds. Collect the expelled liquid with a tissue.



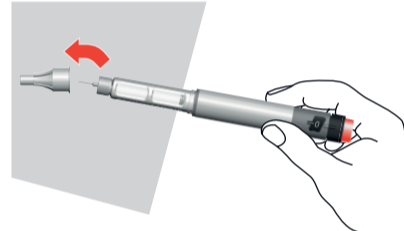
8. Check that the display reads "0" and that this figure is fully visible and centred in the dose window, the white mark and the window notch are aligned, and the dose knob and pen body marks are aligned.



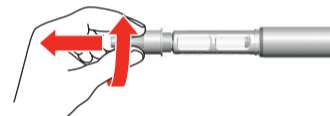
### Removing the Needle

Remove the needle after preparation of the pen, to minimise the risk of infection.

9. Carefully push the needle into the large outer cap. Do not touch the needle.



10. Unscrew the needle by turning the large outer cap anti-clockwise and pull the needle from the pen.



11. Dispose of the needle (in the needle cap) in a sharps container or a hard plastic container with a secure lid as directed by your doctor or pharmacist (see "For your safety" above).

### Keeping the Injection Diary

12. Note the current date and the date of the 28th injection in the Injection Diary on the back of these instructions for use.

Now your pen is prepared for the first and all further injections as described below.

## Injecting the Pen

### Prepare yourself for injection

- Wash your hands before every injection.
- Prepare the injection site (on the thigh or abdomen) as directed by your doctor, pharmacist or carer.

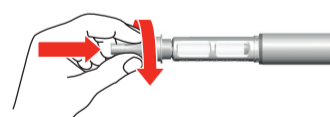
Use a new needle for every injection. A used needle poses a risk of infection.

### Attaching the needle

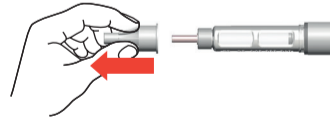
1. Remove the pen cap.
2. Take a new needle and remove the seal foil from the needle cap.



3. Attach the needle with the large outer cap to the pen. Screw the large outer cap clockwise as far as it will go.



4. Remove the large outer cap from the needle and save it.



TECHNICAL COLOUR  
NON PRINTABLE



Approved by: <b>Biotech Pharma Limited</b>	Technical approval by: <b>Manufacturer</b>
---	---

Formatting Criteria	Teriparatide Biotech 20mcg/80µL solution
Single Page Dimensions	180 (W) x 560 (H)
Number of Pages	2
Font Style	Frutiger LT Std
Font Size – Headings	18 pt
Font Size – Sub headings	10 pt
Font Size – Body text	9 pt
Margins	Top/Bottom/Right/Left: 10 mm
Line-spacing	3.9 mm
Pictograms	NA

	JOB NUMBER <b>BP0010/N</b>	JOB CATEGORY <b>NEW</b>	VERSION <b>01</b>	CUSTOMER: <b>BIOTECH PHARMA LIMITED</b>
	DIMENSIONS (mm) <b>180x560</b>	COLOURS: <b>4</b>		PRODUCT: <b>Teriparatide Biotech 20mcg/80µL solution - User guide</b>
TRACKING: <b>22.06.2025</b>				

