

**Applicant:** Eli Lilly (S.A.) (Pty) Limited  
**Proprietary Name(s):** Forteo  
**Active ingredient:** Teriparatide  
**Dosage Form and Strength:** 250 µg/ml

MS8400\_ZA\_PIL\_v01.1\_MTC  
**Date:** 17 March 2022

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

**FORTEO, 250 µg/ml, injection**

**Teriparatide**

**Read all of this leaflet carefully before you start taking FORTEO**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FORTEO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

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

#### **1. What FORTEO is and what it is used for**

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

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FORTEO 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 menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

## **2. What you need to know before you take FORTEO**

### **Do not use FORTEO**

- 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 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 had radiation therapy involving your bones.
- if you are pregnant or breastfeeding.
- 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.

### **Warnings and precautions**

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

Talk to your doctor or pharmacist before or while using FORTEO:

- if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.

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Some patients get dizzy or get a fast heartbeat after the first few doses. For the first doses, inject FORTEO where you can sit or lie down right away if you get dizzy.

The recommended treatment time of 24 months should not be exceeded.

### **Children and adolescents**

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

### **Other medicines and FORTEO**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your healthcare provider if you are taking digoxin/digitalis, a medicine used to treat heart disease.

### **Pregnancy and breastfeeding**

Do not use FORTEO if you are pregnant or breastfeeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of FORTEO. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, FORTEO should be discontinued. Please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

### **Driving and using machines**

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

### **3. How to use FORTEO**

Do not share medicines prescribed for you with any other person.

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

FORTEO can be injected at mealtimes.

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

You should take your FORTEO 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 FORTEO pen with others even if the needle is changed.

Your doctor may advise you to take FORTEO with calcium and vitamin D. Your doctor will tell you

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how much you should take each day.

### **If you use more FORTEO than you should**

If, by mistake, you have used more FORTEO 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 FORTEO 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 FORTEO**

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

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

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reported in association with FORTEO 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:

Frequent side effects:

- 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 breastbone)

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- being sick(vomiting)
- a hernia of the tube that carries food to your stomach
- low haemoglobin or red blood cell count (anaemia)

Less frequent side effects:

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

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s

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publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of FORTEO.

Alternatively, report suspected adverse reactions to the company at [ade\\_za@lilly.com](mailto:ade_za@lilly.com).

## **5. How to store FORTEO**

Store in a refrigerator between 2°C and 8 °C.

Do not freeze. Do not use FORTEO if it has been frozen.

The FORTEO prefilled delivery device should be discarded 28 days after the first injection from the device, even if there is solution left in the pen.

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

Store all medicines out of reach of children.

Do not store in a bathroom

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What FORTEO contains**

The active substance is teriparatide. Each millilitre 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 injection.

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### **What FORTEO looks like and contents of the pack**

FORTEO is a colourless 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 one pen.

### **Holder of Certificate of Registration**

Eli Lilly (S.A.) (Pty) Limited  
1<sup>st</sup> Floor, Golden Oak House  
Ballyoaks Office Park,  
35 Ballyclare Drive  
Bryanston, 2191

### **This leaflet was last revised in**

17 March 2022

### **Registration number**

36/21.4/0334

### **Access to the corresponding Professional Information**

Professional information is included in pack.