

## PART III: CONSUMER INFORMATION

### FORTEO® teriparatide (rDNA origin) injection

This leaflet is part III of a three-part "Product Monograph" published when FORTEO was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FORTEO. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

FORTEO is a prescription medicine used to treat osteoporosis by forming new bone. FORTEO is approved for use in both men and postmenopausal women with severe osteoporosis. FORTEO is also approved for use in both men and women with severe osteoporosis related to use of corticosteroid medicines, such as prednisone, who are at high risk for having broken bones (fractures). These include men and women with either a history of broken bones or those with a low bone mineral density (BMD).

##### What it does:

FORTEO builds new bone faster than the old bone is lost. Your bones become stronger as you continue to use FORTEO, and your risk for fracture will be reduced.

##### When it should not be used:

Only take FORTEO if your doctor has prescribed it for you.

Do not take FORTEO if you:

- have had an allergic reaction to teriparatide or one of its ingredients.
- suffer from high calcium level (pre-existing hypercalcemia).
- suffer from kidney problems (severe renal impairment).
- have other bone diseases.
- have high levels of alkaline phosphatase.
- have had radiation therapy involving your bones.
- have ever been diagnosed with bone cancer or other cancers that have spread (metastasized) to your bones.
- are a child or growing adult.
- are pregnant or breast-feeding.
- have trouble injecting yourself and do not have someone who can help you.

##### What the medicinal ingredient is:

FORTEO contains teriparatide, which is the same as the active part of a natural hormone called parathyroid hormone or "PTH".

##### What the important nonmedicinal ingredients are:

In addition to the active ingredient teriparatide, inactive ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol (preservative), and water for injection. In addition, hydrochloric acid solution and/or sodium hydroxide solution may have been added to adjust product pH.

##### What dosage forms it comes in:

FORTEO is supplied as a sterile solution for subcutaneous injection in a 3 mL glass cartridge pre-assembled into a disposable pen delivery device. Each mL contains 250 mcg teriparatide. Each cartridge pre-assembled into a pen device delivers 20 mcg of FORTEO per dose each day for up to 28 days.

#### WARNINGS AND PRECAUTIONS

##### Serious Warnings and Precautions

As part of drug testing, teriparatide, the active ingredient in FORTEO, was given to rats for a significant part of their lifetime. In these studies, teriparatide caused some rats to develop osteosarcoma, a bone cancer. The potential to cause osteosarcoma in rats was increased with higher doses and longer periods of treatment. Osteosarcoma in humans is a serious but very rare cancer. Osteosarcoma occurs in about 4 out of every million people each year. None of the patients in the clinical trials or post-treatment follow up developed osteosarcomas. Osteosarcoma has been reported rarely in people who took prescription FORTEO. It is not known if people who take FORTEO have a higher chance of getting osteosarcoma. You should discuss any safety concerns you have about the use of FORTEO with your doctor.

#### INTERACTIONS WITH THIS MEDICATION

Tell your health care provider and pharmacist about all the medicines you are taking when you start taking FORTEO, and if you start taking a new medicine after you start FORTEO treatment. Tell them about all medicines you get with prescriptions and without prescriptions, as well as herbal or natural remedies. Your doctor and pharmacist need this information to help keep you from taking a combination of products that may harm you.

#### PROPER USE OF THIS MEDICATION

- Take FORTEO once daily for as long as your doctor prescribes it for you.
- Refer to the Pen User Manual for instructions on how to use the FORTEO pen. The FORTEO prefilled pen injector will deliver a preset dose of 20 mcg.
- Take one subcutaneous injection of FORTEO each day. The injection may be given into the thigh or abdomen.
- FORTEO can be taken at any time of day. To help you remember to take FORTEO, take it at about the same time each day (for example, at bedtime).
- You should take your FORTEO injection shortly after you take it out of the refrigerator as described in the Pen User Manual. A warming period is not needed. Put the pen back into the refrigerator immediately after use.

- If you forget or are unable to take FORTEO at your usual time, take it at your next regularly scheduled time. Do not take more than one injection in the same day.
- Calcium and/or vitamin D may be taken at the same time as FORTEO. You should discuss with your doctor how much calcium and vitamin D to take each day.
- FORTEO can be taken with or without food or drink.
- Keep all medicines, including FORTEO, away from children.
- The FORTEO pen contains a sterile, colorless, clear solution. Do not use if solid particles appear or if the solution is cloudy or coloured. FORTEO should never be used beyond the date indicated on the carton.
- Never share a FORTEO pen with others, even if they have a similar disease. Their doctor should decide if FORTEO is right for them. FORTEO has been prescribed just for you.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Most of the side effects of FORTEO are mild. The most common side effects of FORTEO are dizziness, nausea, pain in and around joints, and leg cramps.
- If you become dizzy do not drive or operate machinery; you should sit or lie down until the symptoms go away. If symptoms continue or get worse, you should call a doctor before continuing treatment.
- Contact your health care provider 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 have any problems or questions while taking FORTEO, ask your doctor, nurse, or pharmacist for more information.

### HOW TO STORE IT

- Your FORTEO pen should be stored in the refrigerator between 2°C to 8°C at all times.
- Your FORTEO pen can be used for up to 28 days including the first injection from the pen.
- The FORTEO pen should be properly disposed of after 28 days of first use, even if it is not completely empty.
- Do not freeze. Do not use FORTEO if it has been frozen.

### REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada, through the Canada Vigilance Program, collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
 toll-free telephone: 866-234-2345  
 toll-free fax 866-678-6789

Postage Paid Mail:

Canada Vigilance Program  
 Health Canada  
 Address Locator: 0701C  
 Ottawa, ON K1A 0K9

***NOTE: Should you require information related to the management of the side effect, please contact your health care provider. The Canada Vigilance Program does not provide medical advice.***

### MORE INFORMATION

For more information, please contact your doctor or pharmacist first or the FORTEO Customer Care program at 1-877-4FORTEO (1-877-436-7836).

This leaflet was prepared by Eli Lilly Canada Inc., Toronto, Ontario, M1N 2E8.

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