

Medication Guide

FORTEO™

Generic name: teriparatide (rDNA origin) injection

Read this information carefully before you start taking FORTEO (for-TAY-o) to learn about the benefits and risks of FORTEO. Before beginning therapy, read the FORTEO pen User Manual for information on how to use the pen to inject your medicine. Read the information you get with FORTEO each time you get a refill, in case something has changed. Talk with your health care provider if there is something you do not understand or if you want to learn more about FORTEO.

What is the most important information I should know about FORTEO?

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.** Osteosarcoma in humans is a serious but very rare cancer. Osteosarcoma occurs in about 4 out of every million older adults each year. **It is not known if humans treated with FORTEO also have a higher chance of getting osteosarcoma.**

FORTEO is approved for use in both men and postmenopausal (after the “change of life”) women with osteoporosis who are at high risk for having broken bones (fractures) from osteoporosis.

Before starting treatment, talk with your doctor about the possible benefits and risks of FORTEO so you can decide if it is right for you.

What is osteoporosis?

Osteoporosis is a disease in which the bones become thin and weak, increasing the chance of having a broken bone. Osteoporosis usually causes no symptoms until a fracture happens. The most common fractures are in the spine (backbone). They can shorten height, even without causing pain. Over time, the spine can become curved or deformed and the body bent over. Fractures from osteoporosis can also happen in almost any bone in the body, for example, the wrist, rib, or hip. Once you have had a fracture, the chance for more fractures greatly increases.

The following risk factors increase your chance of getting fractures from osteoporosis:

- past broken bones from osteoporosis
- very low bone mineral density (BMD)
- frequent falls
- limited movement, such as using a wheelchair
- medical conditions likely to cause bone loss, such as some kinds of arthritis
- medicines that may cause bone loss, for example: seizure medicines (such as phenytoin), blood thinners (such as heparin), steroids (such as prednisone), high doses of vitamins A or D.

What is FORTEO?

FORTEO is a prescription medicine used to treat osteoporosis by forming new bone. FORTEO is the brand name for teriparatide, which is the same as the active part of a natural hormone called parathyroid hormone or “PTH.” FORTEO forms new bone, increases bone mineral density and bone strength, and as a result, reduces the chance of getting a fracture. In a study of postmenopausal (after the “change of life”) women with osteoporosis, FORTEO reduced the number of fractures of the spine and other bones. The effect on fractures has not been studied in men.

FORTEO is approved for use in both men and postmenopausal women with osteoporosis who are at high risk for having fractures. FORTEO can be used by people who have had a fracture related to osteoporosis, or who have multiple risk factors for fracture (See “What is osteoporosis?”), or who cannot use other osteoporosis treatments.

Who should not use FORTEO?

Do not use FORTEO if you:

- have Paget’s disease of the bone
- have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget’s disease. If you are not sure, ask your doctor.
- are a child or growing adult
- have ever been diagnosed with bone cancer or other cancers that have spread (metastasized) to your bones
- have had radiation therapy involving your bones
- have certain bone diseases. If you have a bone disease, tell your doctor.
- have too much calcium in your blood (hypercalcemia)
- are pregnant or nursing
- have had an allergic reaction to FORTEO or one of its ingredients (See the ingredients section at the end of this Medication Guide)
- have trouble injecting yourself and do not have someone who can help you.

FORTEO should not be used to prevent osteoporosis or to treat patients who are not considered to be at high risk for fracture.

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.

How should I take FORTEO?

- Take FORTEO once a day for as long as your doctor prescribes it for you. Use of FORTEO for more than 2 years is not recommended. Your health care professional (doctor, nurse, or pharmacist) should teach you how to use the FORTEO pen (prefilled delivery device). (See the User Manual for written instructions on how to use the FORTEO pen.)
- Some patients get dizzy or get a fast heartbeat after the first few doses. For the first few doses, inject FORTEO where you can sit or lie down right away if you get dizzy.

- Inject FORTEO once each day in your thigh or abdomen (lower stomach area).
- You can take FORTEO with or without food or drink.
- You can take FORTEO at any time of the day. To help you remember to take FORTEO, take it at about the same time each day.
- Do not use FORTEO if it has solid particles in it, or if it is cloudy or colored. It should be clear and colorless.
- Do not use FORTEO after the expiration date printed on the pen and pen packaging.
- Throw away any FORTEO pen that you started using more than 28 days earlier, even if it still has medicine in it (See the User Manual).
- Inject FORTEO shortly after you take the pen out of the refrigerator. Recap the pen and put it back into the refrigerator right after use (See the User Manual).
- If you forget or are unable to take FORTEO at your usual time, take it as soon as possible on that day. Do not take more than one injection in the same day.
- Talk with your health care provider about other ways you can help your osteoporosis, such as exercise, diet, supplements, and reducing or stopping your use of tobacco and alcohol. If your health care provider recommends calcium and vitamin D supplements, you can take them at the same time as FORTEO.

What are the possible side effects of FORTEO?

Most side effects are mild and include dizziness and leg cramps. If you become lightheaded or have fast heartbeats after your injection, sit or lie down until you feel better. If you do not feel better, call your health care provider 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.

These are not all the possible side effects of FORTEO. For more information, ask your health care provider or pharmacist.

Your health care provider may take samples of blood and urine during treatment to check your response to FORTEO. Also, your health care provider may ask you to have follow-up tests of bone mineral density.

How should I store FORTEO?

- Keep your FORTEO pen in the refrigerator at 36° to 46°F (2° to 8°C).
- Do not freeze the pen. Do not use FORTEO if it has been frozen.
- You can use your FORTEO pen for up to 28 days after the first injection from the pen.
- Throw away the pen properly (See the User Manual) after 28 days of use, even if it is not completely empty.
- Recap the pen after each use (See the User Manual) to protect from physical damage.

General information about using FORTEO safely and effectively

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use FORTEO for a condition for which it was not prescribed. Do not give FORTEO to other people, even if they have the same condition you have.

This Medication Guide summarizes the most important information about FORTEO. If you would like more information, talk with your doctor, nurse, or pharmacist. You can ask your pharmacist or health care provider for information about FORTEO that is written for health care professionals. You can also call Lilly toll free at 1-866-4FORTEO (1-866-436-7836).

Ingredients

In addition to the active ingredient teriparatide, inactive ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, Metacresol, and Water for Injection. In addition, hydrochloric acid solution 10% and/or sodium hydroxide solution 10% may have been added to adjust product pH.

This Medication Guide has been approved by the US Food and Drug Administration.

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