

The safety and efficacy of FORTEO have not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years is not recommended.

INSTRUCTIONS FOR PEN USE

Patients and caregivers who administer FORTEO should receive appropriate training and instruction on the proper use of the FORTEO delivery device from a qualified health professional. It is important to read, understand, and follow the instructions in the FORTEO delivery device *User Manual*. Failure to do so may result in inaccurate dosing. Each FORTEO delivery device can be used for up to 28 days, including the first injection from the pen. After the 28-day use period, discard the FORTEO delivery device, even if it still contains some unused solution. Never share a FORTEO delivery device.

STORAGE

The FORTEO delivery device should be stored under refrigeration at 2° to 8°C (36° to 46°F) at all times. Recap the pen when not in use to protect the cartridge from physical damage and light. During the use period, time out of the refrigerator should be minimized; the dose may be delivered immediately following removal from the refrigerator.

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

HOW SUPPLIED

The FORTEO delivery device is available in the following:

- 3 mL prefilled pen delivery device NDC 0002-8971-01 (MS8971)
- 2.4 mL prefilled pen delivery device NDC 0002-8400-01 (MS8400).

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Manufactured by Lilly France - F-67640 Fegersheim, France

for Eli Lilly and Company - Indianapolis, IN 46285, USA

www.forteo.com

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Medication Guide

FORTEO[®] (for-TAY-o) teriparatide (rDNA origin) injection

Read this Medication Guide carefully before you start taking FORTEO and each time you get a refill. The information may have changed. Also, read the User Manual that comes with the FORTEO delivery device (pen) for information on how to use the device to inject your medicine the right way. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment. Ask your healthcare provider if there is something you do not understand or if you want to learn more about the benefits and risks of 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.**

What is FORTEO?

FORTEO is a prescription medicine that contains teriparatide, a man-made medicine that is like the natural hormone called parathyroid hormone or PTH. PTH is produced by the body. FORTEO forms new bone, increases bone mineral density and bone strength. This lowers the chance of getting a fracture. In postmenopausal (after the “change of life”) women with osteoporosis, FORTEO can lessen the number of fractures of the spine and other bones. The effect on fractures has not been studied in men. FORTEO is used 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, or who cannot use other osteoporosis treatments.

FORTEO has not been studied in children.

Who should not use FORTEO?

Do not use FORTEO if you:

- are allergic to any of the ingredients in FORTEO. See the end of this Medication Guide for a complete list of the ingredients in FORTEO.
- have Paget's disease of bone.
- have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget's disease of bone. 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).

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

What should I tell my healthcare provider before taking FORTEO?

Tell your healthcare provider about all of your medical conditions, including if you:

- have one of the conditions listed in the section “Who should not use FORTEO?”
- have trouble injecting yourself and do not have someone who can help you.
- have or have had kidney stones.
- are pregnant or thinking about becoming pregnant. It is not known if FORTEO will harm your unborn baby.
- are breast-feeding or thinking about breast-feeding. It is not known if FORTEO passes into breast milk. You should not breast-feed while taking FORTEO.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Your healthcare provider needs this information to help keep you from taking FORTEO with other medicines that may harm you.

- Especially tell your doctor if you take medicines that contain digoxin (for example, Digoxin, Lanoxicaps, Lanoxin).

How should I use FORTEO?

- Use FORTEO one time each day. Your healthcare provider should teach you how to use the FORTEO delivery device (see the User Manual).
- The use of FORTEO for more than 2 years is not recommended.
- The FORTEO delivery device has enough medicine for 28 days. It is set to give a 20 microgram dose of medicine each day (see the User Manual). Do not inject all the medicine in the FORTEO delivery device at any one time.
- Do not transfer the contents of the FORTEO delivery device to a syringe. This can result in taking the wrong dose of FORTEO. If you do not have pen needles available to use with your FORTEO delivery device, talk with your healthcare provider.
- Inject FORTEO one time each day in your thigh or abdomen (lower stomach area). Talk to your healthcare provider about how to rotate injection sites.
- FORTEO should look clear and colorless. Do not use FORTEO if it has particles in it, or if it is cloudy or colored.
- Inject FORTEO right away after you take the delivery device out of the refrigerator.
- After each use, safely remove the needle, recap the delivery device, and put it back in the refrigerator right away (see the User Manual).
- 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.
- If you forget or are unable to take FORTEO at your usual time, take it as soon as you can on that day. Do not take more than one injection in the same day.

Follow your healthcare provider's instructions about other ways you can help your osteoporosis, such as exercise, diet, and reducing or stopping your use of tobacco and alcohol. If your healthcare provider recommends calcium and vitamin D supplements, you can take them at the same time you take FORTEO.

What are the possible side effects of FORTEO?

Most side effects are mild and include:

- nausea.

- dizziness or fast heartbeat. Some people get dizzy or get a fast heartbeat right after the first few doses. This usually happens within 4 hours of taking FORTEO and goes away within a few hours. For the first few doses, take your injections of FORTEO in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, stop taking FORTEO and call your healthcare provider.
- leg cramps.
- joint aches.
- increased calcium in your blood. Tell your healthcare 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.
- injection site reactions including redness, swelling, pain, itching, a few drops of blood, and bruising.

Your healthcare provider may take samples of blood and urine during treatment to check your response to FORTEO. Also, your healthcare provider may ask you to have follow-up tests of bone mineral density. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of FORTEO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FORTEO?

- Keep your FORTEO delivery device in the refrigerator at 36° to 46°F (2° to 8°C).
- Do not freeze the FORTEO delivery device. Do not use FORTEO if it has been frozen.
- Do not use FORTEO after the expiration date printed on the delivery device and packaging.
- Throw away the FORTEO delivery device after 28 days even if it has medicine in it (see the User Manual).

General information about FORTEO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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 healthcare provider. You can ask your pharmacist or healthcare provider for information about FORTEO that is written for healthcare professionals. For more information, go to www.FORTEO.com or call Lilly toll free at 1-866-4FORTEO (1-866-436-7836).

What are the ingredients in FORTEO?

Active ingredient: teriparatide

Inactive ingredients: 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 the product to pH 4.

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, high doses of vitamin A.

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

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