

MEDICATION GUIDE
FORTEO® (for-TAY-o)
teriparatide injection
for subcutaneous use

Read this Medication Guide before you start using FORTEO and each time you get a refill. There may be new information. 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.

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

Possible bone cancer. During drug testing, the medicine in FORTEO caused some rats to develop a bone cancer called osteosarcoma. Studies in people have not shown that FORTEO increases your chance of getting osteosarcoma. There is little information about the chance of getting osteosarcoma in patients using FORTEO beyond 2 years.

What is FORTEO?

FORTEO is a prescription medicine used to:

- treat postmenopausal women who have osteoporosis who are at high risk for having broken bones (fractures) or who cannot use other osteoporosis treatments. FORTEO can lessen the chance of broken bones (fractures) in the spine and other bones in postmenopausal women with osteoporosis.
- increase the bone mass in men with primary or hypogonadal osteoporosis who are at high risk for having broken bones (fractures) or who cannot use other osteoporosis treatments.
- treat both men and women with osteoporosis due to use of glucocorticoid medicines, such as prednisone, for several months, who are at high risk for having broken bones (fractures) or who cannot use other osteoporosis treatments.

It is not known if FORTEO is safe and effective in children.

FORTEO should not be used in children and young adults whose bones are still growing.

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.

Symptoms of a serious allergic reaction of FORTEO may include swelling of the face, lips, tongue or throat that may cause difficulty in breathing or swallowing. Call your healthcare provider right away or get emergency medical help if you get any of these symptoms.

What should I tell my healthcare provider before using FORTEO?

Before you use FORTEO, tell your healthcare provider about all of your medical conditions, including if you:

- have a certain bone disease called Paget's disease or other bone disease.
- have bone cancer or have had a history of bone cancer.
- are a young adult whose bones are still growing.
- have had radiation therapy.
- are affected with a condition that runs in your family that can increase your chance of getting cancer in your bones.
- have or have had too much calcium in your blood (hypercalcemia).
- have or have had a skin condition with painful sores or wounds caused by too much calcium.
- have or have had kidney stones.
- take medicines that contain digoxin.
- are pregnant or plan to become pregnant. It is not known if FORTEO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if FORTEO passes into your breastmilk. You should not breastfeed while taking FORTEO.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use FORTEO?

- Read the detailed Instructions for Use (User Manual) included with your FORTEO delivery device.
- Use FORTEO exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much FORTEO to use and when to use it.
- Before you try to inject FORTEO yourself, a healthcare provider should teach you how to use the FORTEO delivery device to give your injection the right way.
- Inject FORTEO 1 time each day in your thigh or abdomen (lower stomach area). Do not inject into a vein or a muscle. Talk to a healthcare provider about how to rotate injection sites.
- The FORTEO delivery device has enough medicine for 28 days. It is set to give a 20-microgram dose of medicine each day. Do not inject all the medicine in the FORTEO delivery device at any one time.

- Do not transfer the medicine from the FORTEO delivery device to a syringe. This can result in taking the wrong dose of FORTEO. If you do not have pen needles to use with your FORTEO delivery device, talk with your healthcare provider.
- 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.
- When you inject the first few doses of FORTEO, make sure you are in a place where you can sit or lie down right away in case you feel dizzy or have an abnormal heartbeat after the injection.
- Do not take more than 1 injection in the same day.
- Do not share your FORTEO delivery device with other people.
- If you take more FORTEO than prescribed, call your healthcare provider. If you take too much FORTEO, you may have nausea, vomiting, weakness, or dizziness.
- You should not use FORTEO for more than 2 years over your lifetime unless your healthcare provider finds that you need longer treatment because you have a high chance of breaking your bones.

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?

FORTEO may cause serious side effects including:

- See “**What is the most important information I should know about FORTEO?**”
- **Bone cancer (osteosarcoma):** Tell your healthcare provider right away if you have pain in your bones, pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that is tender to touch.
- **Increased calcium in your blood.** Tell your healthcare provider if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- **Worsening of your kidney stones.** If you have or have had kidney stones your healthcare provider may check the calcium levels in your urine while you use FORTEO to see if there is worsening of this condition.
- **Decrease in blood pressure when you change positions.** Some people may feel dizzy, get a fast heartbeat, or feel light-headed right after the first few doses of FORTEO. This usually happens within 4 hours of taking FORTEO and goes away within a few hours. For the first few doses, give 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, contact your healthcare provider before you continue using FORTEO.

The most common side effects of FORTEO include:

- pain
- nausea
- joint aches

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

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?

- Store FORTEO in the refrigerator between 36°F to 46°F (2°C to 8°C) until ready to use. Use FORTEO right away after you remove it from the refrigerator.
- Do not freeze FORTEO. Do not use FORTEO if it has been frozen.
- Throw away the FORTEO delivery device after 28 days even if it has medicine in it (see the User Manual).
- Do not use FORTEO after the expiration date printed on the delivery device and packaging.
- Recap FORTEO when not in use to protect it from physical damage and light.

Keep FORTEO and all medicines out of the reach of children.

General information about the safe and effective use of 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 symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about FORTEO that is written for health professionals.

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.

For more information, go to www.FORTEO.com or call Lilly at 1-866-436-7836.

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