

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.

- 41 • have had radiation therapy involving your bones.
- 42 • have certain bone diseases. If you have a bone disease, tell your doctor.
- 43 • have too much calcium in your blood (hypercalcemia).

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

46 **What should I tell my healthcare provider before taking FORTEO?**

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

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

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

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

61 **How should I use FORTEO?**

- 62 • Use FORTEO one time each day. Your healthcare provider should teach you how
63 to use the FORTEO delivery device (see the User Manual).
- 64 • The use of FORTEO for more than 2 years is not recommended.
- 65 • The FORTEO delivery device has enough medicine for 28 days. It is set to give a
66 20 microgram dose of medicine each day (see User Manual). Do not inject all the
67 medicine in the FORTEO delivery device at any one time.
- 68 • Do not transfer the contents of the FORTEO delivery device to a syringe. This
69 can result in taking the wrong dose of FORTEO. If you do not have pen needles
70 available to use with your FORTEO delivery device, talk with your healthcare
71 provider.
- 72 • Inject FORTEO one time each day in your thigh or abdomen (lower stomach
73 area). Talk to your healthcare provider about how to rotate injection sites.
- 74 • FORTEO should look clear and colorless. Do not use FORTEO if it has particles
75 in it, or if it is cloudy or colored.
- 76 • Inject FORTEO right away after you take the delivery device out of the
77 refrigerator.
- 78 • After each use, safely remove the needle, recap the delivery device, and put it
79 back in the refrigerator right away (see the User Manual).
- 80 • You can take FORTEO with or without food or drink.

- 81 • You can take FORTEO at any time of the day. To help you remember to take
82 FORTEO, take it at about the same time each day.
- 83 • If you forget or are unable to take FORTEO at your usual time, take it as soon as
84 you can on that day. Do not take more than one injection in the same day.
- 85 Follow your healthcare provider's instructions about other ways you can help your
86 osteoporosis, such as exercise, diet, and reducing or stopping your use of tobacco and
87 alcohol. If your healthcare provider recommends calcium and vitamin D supplements,
88 you can take them at the same time you take FORTEO.

89 **What are the possible side effects of FORTEO?**

90 Most side effects are mild and include:

- 91 • nausea.
- 92 • dizziness or fast heartbeat. Some people get dizzy or get a fast heartbeat right
93 after the first few doses. This usually happens within 4 hours of taking FORTEO
94 and goes away within a few hours. For the first few doses, take your injections of
95 FORTEO in a place where you can sit or lie down right away if you get these
96 symptoms. If your symptoms get worse or do not go away, stop taking FORTEO
97 and call your healthcare provider.
- 98 • leg cramps.
- 99 • joint aches.
- 100 • increased calcium in your blood. Tell your healthcare provider if you have
101 continuing nausea, vomiting, constipation, low energy, or muscle weakness.
102 These may be signs there is too much calcium in your blood.
- 103 • injection site reactions including redness, swelling, pain, itching, a few drops of
104 blood, and bruising.

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

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

111 **How should I store FORTEO?**

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

119 **General information about FORTEO**

120 Medicines are sometimes prescribed for purposes other than those listed in a Medication
121 Guide. Do not use FORTEO for a condition for which it was not prescribed. Do not give
122 FORTEO to other people, even if they have the same condition you have.

123 This Medication Guide summarizes the most important information about FORTEO. If
124 you would like more information, talk with your healthcare provider. You can ask your
125 pharmacist or healthcare provider for information about FORTEO that is written for
126 healthcare professionals. For more information, go to www.FORTEO.com or call Lilly toll
127 free at 1-866-4FORTEO (1-866-436-7836).

128 **What are the ingredients in FORTEO?**

129 Active ingredient: teriparatide

130 Inactive ingredients: glacial acetic acid, sodium acetate (anhydrous), mannitol,
131 metacresol, and water for injection. In addition, hydrochloric acid solution 10% and/or
132 sodium hydroxide solution 10% may have been added to adjust the product to pH 4.

133 **What is Osteoporosis?**

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

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

- 142 • past broken bones from osteoporosis.
- 143 • very low bone mineral density (BMD).
- 144 • frequent falls.
- 145 • limited movement, such as using a wheelchair.
- 146 • medical conditions likely to cause bone loss, such as some kinds of arthritis.
- 147 • medicines that may cause bone loss, for example: seizure medicines (such as
148 phenytoin), blood thinners (such as heparin), steroids, high doses of vitamin A.
149

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

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