
Appendix 1. Medication Guide

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

Read this Medication Guide before you start taking 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?

1. **Possible bone cancer.** During drug testing, the medicine in FORTEO caused some rats to develop a bone cancer called osteosarcoma. In people, osteosarcoma is a serious but rare cancer. Osteosarcoma has rarely been reported in people who took FORTEO. It is not known if people who take FORTEO have a higher chance of getting osteosarcoma.
2. You should not take FORTEO for more than 2 years over your lifetime.
3. **There is a voluntary Patient Registry for people who take FORTEO.** The purpose of the registry is to collect information about the possible risk of osteosarcoma in people who take FORTEO. For information about how to sign up for this patient registry, call 1-866-382-6813 or go to www.forteoregistry.rti.org.

What is FORTEO?

- FORTEO is a prescription medicine that is like a hormone made by the body called parathyroid hormone or PTH. FORTEO may help to form new bone, increase bone mineral density and bone strength.
- FORTEO can lessen the number of fractures of the spine and other bones in postmenopausal women with osteoporosis.
- 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 several risk factors for fracture, or who can not use other osteoporosis treatments.
- FORTEO is used in 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). These include men and women with either a history of broken bones, who have several risk factors for fracture, or who can not 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.

Forteo Medication Guide

IM Harris



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