Highlighted Information for Prescribers

POTENTIAL RISK OF OSTEOSARCOMA AND THE VOLUNTARY FORTEO PATIENT REGISTRY
HIGHLIGHTED INFORMATION FOR PRESCRIBERS

Potential Risk of Osteosarcoma and the Voluntary FORTEO Patient Registry

This information is being provided to prescribers of FORTEO as part of the Risk Evaluation and Mitigation Strategy (REMS) plan for FORTEO. REMS plans have been required for certain drugs with serious risks since 2008 by the U.S. Food and Drug Administration to ensure that the benefits of the drug outweigh the risks of the drug.

The purpose of this information is to inform prescribers of FORTEO about the following:
• Proper patient selection and 2-year maximum lifetime duration of treatment
• Potential risk of osteosarcoma
• Voluntary FORTEO Patient Registry

Refer to the Full Prescribing Information and Medication Guide for further product information.

INDICATIONS AND USAGE

• FORTEO is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.*
• FORTEO is indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture.*
• FORTEO is indicated for the treatment of men and women with osteoporosis associated with sustained, systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture.*

*High risk for fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

FORTEO is administered as a 20 microgram once daily dose and is available in a 2.4 mL prefilled delivery device for subcutaneous injection over 28 days.

TREATMENT DURATION

The safety and efficacy of FORTEO have not been evaluated beyond 2 years of treatment. The use of FORTEO for more than 2 years during a patient’s lifetime is, therefore, not recommended.
POTENTIAL RISK OF OSTEOSARCOMA

FORTEO labeling contains a boxed warning describing the potential risk of osteosarcoma:

• In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20-mcg dose.

• Because of the uncertain relevance of the rat osteosarcoma finding to humans, FORTEO should be prescribed only to patients for whom the potential benefits are considered to outweigh the potential risk.

• FORTEO should not be prescribed for patients who are at increased baseline risk for osteosarcoma including:
  ◦ Those with Paget’s disease of bone or unexplained elevations of alkaline phosphatase
  ◦ Pediatric and young adult patients with open epiphyses
  ◦ Prior external beam or implant radiation therapy involving the skeleton

Additional warnings and precautions in the label state that patients with the following conditions should not receive FORTEO:

• Bone metastases or a history of skeletal malignancies
• Metabolic bone diseases other than osteoporosis
• Pre-existing hypercalcemia

POSTMARKETING EXPERIENCE: OSTEOSARCOMA

Cases of bone tumor and osteosarcoma have been reported rarely in the postmarketing period. The causality to FORTEO use is unclear.

VOLUNTARY FORTEO PATIENT REGISTRY

Please encourage your patients to join the voluntary FORTEO Patient Registry. This registry was established to collect information about any potential risk of osteosarcoma in patients who have taken FORTEO. A one-time enrollment links your patient to participating state cancer registries for up to 12 years.

We want you to know that RTI International, a non-profit research company, is conducting this safety study on behalf of Eli Lilly and Company, the makers of FORTEO. Your patient’s personal information, including any data that can identify patients, will not be shared with Eli Lilly and Company or anyone outside the research team, without the patient’s permission.

Targeted patient information, including name, address, date of birth, and last 4 digits of social security number, will be provided by patients one time only for entry into the registry. Annually for 12 years, this information will be linked by a secure process to participating state cancer registry databases. Currently, state cancer registries capture newly diagnosed cases of cancer.

Data from this linkage will be analyzed along with information from other studies to help evaluate whether FORTEO patients have an increased risk for developing osteosarcoma. The results will be published after the last linkage. Patients who do not wish to participate in the registry can still receive FORTEO treatment.

Patient participation is voluntary and involves a three-step process:

• Step 1: Patient completes the brief information on the pre-enrollment card.
• Step 2: After the pre-enrollment card is received, the patient will be mailed a one-page informed consent form, a short registration form, and a $5 token of appreciation for the patient’s time in completing the forms.
• Step 3: Patient returns the informed consent and registration forms back to the voluntary FORTEO Patient Registry.

Pre-enrollment forms are available in each filled FORTEO prescription and may also be obtained from FORTEO prescribers. Patients can also access enrollment forms and additional registry information through multiple channels, including: starter kit, website, and patient educational brochures. Healthcare providers may obtain further information about the registry or request pre-enrollment forms by calling the RTI registry hotline at 1-866-382-6813 or visiting www.forteoregistry.rti.org.