Dear Healthcare Professional:

Eli Lilly and Company (Lilly) wishes to inform you of important safety information and updates to the Prescribing Information for FORTEO (teriparatide [rDNA origin] injection). FORTEO is indicated for treatment of postmenopausal women with osteoporosis at high risk for fracture and increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture.

The label includes information regarding the new indication for the treatment of men and women with glucocorticoid-induced osteoporosis (GIO) at high risk for fracture and appropriate patient selection. The label has included a boxed warning concerning the potential risk of osteosarcoma since the approval of FORTEO in 2002. Because patients with GIO may be younger than those currently receiving FORTEO, the language in the boxed warning has been updated to reinforce that FORTEO should not be used in pediatric and young adult patients with open epiphyses.

Cases of bone tumor and osteosarcoma have been reported rarely in the post marketing period. The causality to FORTEO use is unclear. Osteosarcoma is a serious but rare cancer. The incidence in the general population over the age of 60 in the United States is approximately 4 per million per year. The incidence of osteosarcoma in patients taking FORTEO is unknown.

Also included in the label is information regarding the new voluntary patient registry. Patients should be encouraged to enroll in the voluntary FORTEO Patient Registry, which is designed to collect information about any potential risk of osteosarcoma in patients who have taken FORTEO.

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. The clinical relevance of the rat osteosarcoma finding to humans is unknown.

- 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 at increased baseline risk for osteosarcoma, including those with Paget’s disease of bone, unexplained elevations of alkaline phosphatase, pediatric patients or young adults with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton. Additionally, patients with bone metastases or a history of...
skeletal malignancies, metabolic bone diseases other than osteoporosis, or pre-existing hypercalcemia should not receive FORTEO.

Treatment Duration

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 during a patient’s lifetime is not recommended.

INTRODUCTION OF NEW FORTEO® PATIENT REGISTRY

A new voluntary FORTEO Patient Registry has been implemented to supplement ongoing long-term safety studies. We ask that you encourage patients that you are treating with FORTEO to enroll in the registry. Patients can enroll themselves and the burden of enrolling is minimal (3 to 5 minutes). No further action is required of you, beyond encouraging patients to participate.

RTI International (RTI), a nonprofit research organization, is conducting the registry study. All information collected as part of the registry will be kept strictly confidential by RTI, and information that can identify patients will not be shared with Eli Lilly and Company (Lilly), the sponsor of this registry, or with anyone outside of the research team.

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. Each year for 12 years, information provided by patients to RTI will be linked by a secure process to participating state cancer registries that capture information on newly diagnosed cases of cancer. The information will be analyzed along with information from other studies to help evaluate whether FORTEO users have an increased risk for developing osteosarcoma compared to the general population.

The success of the evaluation is dependent on a high participation rate among FORTEO users, so we ask that you encourage your patients to participate. The results will be made publicly available after completion of the study. Patients who do not wish to participate in the registry can still receive FORTEO treatment.

Participation of patients is voluntary and will involve only three steps:

Step 1: Patient completes brief information on the pre-enrollment form.

Step 2: After the pre-enrollment form is received, RTI will mail the patient a two-page informed consent document, the short registration form, and $5 as a token of our appreciation for the patient’s time in completing the forms.
Step 3: Patient completes and mails the informed consent document and registration back to RTI and his/her involvement ends.

Pre-enrollment forms are available:

- in the FORTEO prescription package
- from sales representatives
- by calling the RTI registry hotline at 1-866-382-6813
- by visiting www.forteoregistry.rti.org

If you have any questions about the registry or these materials, please call the RTI registry hotline at 1-866-382-6813 or visit www.forteoregistry.rti.org.

To report adverse events among patients taking FORTEO, please call 1-800-LillyRx (1-800-545-5979). Alternatively, adverse event information may be reported to FDA’s MedWatch Reporting System by:

- phone at 1-800-FDA-1088 (1-800-332-1088)
- by facsimile at 1-800-FDA-0178 (1-800-332-0178)
- by mail using FDA Form 3500 at http://www.fda.gov/medwatch/index.html

We urge you to contact our Medical Information department at 1-866-4FORTEO (1-866 436-7836) or visit www.FORTEO.com if you have any questions about the information contained in this letter or the safe and effective use of FORTEO.

Thank you in advance for encouraging patients to enroll in this important registry!

Sincerely,

Donald Therasse, M.D.
Vice President, Global Patient Safety
Eli Lilly and Company

Enclosure: FORTEO Full Prescribing Information [Will revise per FDA approved label]