

Initial REMS Approval: July 2009

Most Recent Modification: August 2013

NDA 21-318
FORTEO® (teriparatide) (rDNA origin) Injection

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Eli Lilly and Company
Indianapolis, IN 46285
Telephone: 317-276-2000

I. Goals

A. Risk Mitigation

To mitigate the potential risk of osteosarcoma associated with FORTEO by:

- i. alerting and warning healthcare providers and patients about the potential risk
- ii. informing healthcare providers of the 2-year maximum lifetime duration of treatment with FORTEO and proper patient selection
- iii. informing and educating healthcare providers and patients about the voluntary FORTEO Patient Registry

II. REMS Elements

A. Medication Guide

A Medication Guide will be dispensed with each FORTEO prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.

B. Communication Plan

In accordance with FDCA 505-1(e)(3), Lilly will implement the following elements of a communication plan to healthcare providers (HCP) likely to prescribe FORTEO:

- i. **A Dear HCP (DHCP) Letter** will be mailed at the time of launch of the glucocorticoid-induced osteoporosis (GIO) indication. The intended audience for this DHCP letter will be all healthcare professionals who are likely to prescribe FORTEO. Lilly has identified these providers as any HCP who has prescribed

FORTEO in the last 12 months. These include physicians, nurse practitioners, and physicians' assistants, predominantly in the specialties of Rheumatology, Endocrinology, Internal Medicine, and Family Practice.

Please see the appended DHCP Letter.

- ii. **A Direct Mail Letter** containing the elements of the DHCP letter will also be mailed once per year for an additional 2 years post launch to all prescribers who newly prescribe FORTEO. These prescribers will be defined as any HCP individuals who prescribe FORTEO in a 12-month period and who had not prescribed FORTEO in the previous 12-month period.

Please see the appended Direct Mail Letter.

- iii. **The Highlighted Information for Prescribers** will be provided by Lilly representatives during the first discussion of the new GIO indication with all HCPs visited during the first 6 months after this indication's launch. This will also be sent with the Direct Mail Letter.

Please see the appended Highlighted Information for Prescribers

Lilly will make the REMS, the DHCP letter, the Medication Guide, the Highlighted Information for Prescribers, and professional labeling available via a REMS-specific linkage from the FORTEO website. The Medication Guide, the Highlighted Information for Prescribers, and professional labeling will also be available via hardcopy from Lilly sales specialists, through Lilly's medical information department, and by calling The Lilly Answers Center.

C. *Timetable for Submission of Assessments*

Lilly will submit REMS Assessments to FDA 18 months, 3 years, and 7 years from the date of initial approval of the Forteo REMS (22 July 2009).

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for the assessment. Lilly will submit each assessment so that it will be received by FDA on or before the due date.