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Eli Lilly and Company
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06 Apr 2015

Subject: Direct Healthcare Professional Communication on Potential risk of osteosarcoma with the use of FORTEO (teriparatide) [rDNA origin]

Dear Healthcare Professional:

Eli Lilly and Company (Lilly) wishes to inform you of important safety information for FORTEO (teriparatide [rDNA origin] injection).

Summary

Based upon previous toxicology findings of osteosarcoma in rats, this letter is to highlight the following:

- There is uncertain relevance of rat osteosarcoma finding to humans
- Teriparatide should not be prescribed for more than 24 months
- Teriparatide should not be prescribed for patients of increased baseline risk of osteosarcoma

Potential Risk of Osteosarcoma

- The label includes warnings, precautions for use and preclinical safety data concerning the potential risk of osteosarcoma.
- In rats, long term administration of teriparatide caused an increase in the incidence of osteosarcoma, a malignant bone tumor.
- Because of the uncertain relevance of the rat osteosarcoma finding to humans, prescribe FORTEO only for patients for whom potential benefits outweigh potential risk. Until further clinical data become available, the recommended treatment time of 24 months should not be exceeded.
- FORTEO should not be prescribed for patients 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, 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 hypocalcemia should not receive FORTEO.) .

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FORTEO is indicated for treatment of osteoporosis in postmenopausal women and in men at increased risk for fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated. FORTEO is also indicated for treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.

The information in this letter has been approved by the Saudi Food and Drug Authority.

Call for reporting

To report adverse events among patients taking FORTEO, please contact:

- The National Pharmacovigilance and Drug Safety Center (NPC):

  - Fax: +966-11-205-7662
  - Toll free phone: 8002490000
  - E-mail: npc.drug@sfda.gov.sa
  - Or by online: https://ade.sfda.gov.sa/

- Pharmacovigilance department in Eli Lilly and Company (Lilly):
  - Email :(Saudi_Pharmacovigilance@lilly.com).
  - Fax: +966 1 217 9900

Sincerely,

Robert Baker, M.D.
Vice President, Global Patient Safety
Eli Lilly and Company

On behalf,

Abdullah Al-Abdulwahed
Regulatory Manager, SA
Eli Lilly and Company