The FORTEO Delivery Device just got simpler to use

FORTÉO™
teriparatide (rDNA origin) injection

NEW BONE. NEW STRENGTH.

Dear Pharmacist:

Eli Lilly and Company is pleased to announce the upcoming launch of the new FORTEO Delivery Device. With fewer steps, the new delivery device is designed to be simpler for patients to use.

What's new?

- The priming and setting (dialing) steps have been eliminated, making the delivery device simpler to use
- Color-coded parts are intended to enhance patient training and communication

What's not?

- The new FORTEO Delivery Device uses the same needles, delivers the same dose, and holds the same 28-day supply of FORTEO® (teriparatide [rDNA origin] injection) as the existing delivery device
- Insurance coverage for the new delivery device should not change. If your patient's insurance has not changed, the cost should remain the same as before

Stocking information for the new FORTEO Delivery Device

The new FORTEO Delivery Device will be available for shipping to wholesalers beginning October 15, 2008. Customers may now place their order for the new FORTEO Delivery Device through the normal ordering process. Product information is below to assist you.

Packaging	Carton Dimensions	Product Code
New FORTEO Delivery Device 20 mcg per dose	3.01 x 1.34 x 7.36 in	NDC0002-8400-01

Please note: the FORTEO Pen, 750 mcg/3 mL (NDC0002-8971-01), is no longer being manufactured.

If you or your patients have questions about the new FORTEO Delivery Device, please call the FORTEO Customer CARE center at **1-866-4-FORTEO** for ongoing support.

Sincerely,
Eli Lilly and Company

PS: More information is also available at www.forteo.com (passcode: NEWBONE).

Please see Boxed Warning and Important Safety Information on the back, and provided full Prescribing Information.

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Important Safety Information

WARNING

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, teriparatide should be prescribed only to patients for whom the potential benefits are considered to outweigh the potential risk. Teriparatide 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, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton) (see WARNINGS and PRECAUTIONS, Carcinogenesis).

FORTEO® (teriparatide [rDNA origin] injection) is indicated:

- For the treatment of postmenopausal women with osteoporosis who are at high risk for fracture. These include women with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant of previous osteoporosis therapy, based upon physician assessment (see BOXED WARNING). In postmenopausal women with osteoporosis, FORTEO increases BMD and reduces the risk of vertebral and nonvertebral fractures

- To increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. These include men with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or who have failed or are intolerant to previous osteoporosis therapy, based upon physician assessment (see BOXED WARNING). In men with primary or hypogonadal osteoporosis, FORTEO increases BMD. The effects of FORTEO on risk for fracture in men have not been studied

CONTRAINDICATIONS

Hypersensitivity to teriparatide or to any of its excipients.

WARNINGS

The following categories of patients have increased baseline risk of osteosarcoma and therefore should not be treated with FORTEO:

- Paget's disease of bone
- Pediatric populations and young adults with open epiphyses
- Prior external beam or implant radiation therapy involving the skeleton

Patients with the following conditions also should not receive FORTEO:

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

PRECAUTIONS

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 is not recommended.

In clinical pharmacology studies with FORTEO, there were rare, randomly occurring episodes of symptomatic orthostatic hypotension. Such episodes typically occurred within the first several doses, were relieved by patients assuming a reclining position, and did not preclude continued treatment.

FORTEO may increase serum calcium and urinary calcium. In clinical trials, neither sustained hypercalcemia nor hypercalciuria were observed. Physicians should measure serum calcium at least 16 hours post-dose if sustained hypercalcemia of any etiology is suspected.

ADVERSE EVENTS

The most common side effects associated with FORTEO are nausea, dizziness, leg cramps, joint aches, and injection site reactions.

INSTRUCTIONS FOR FORTEO USE

FORTEO is provided as a multidose, prefilled delivery device that can be used for up to 28 days, including the first injection. The delivery device contains 28 daily doses of 20 mcg each.

Do not transfer the contents of the delivery device into a syringe.

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