



TERIPARATIDE (Forteo[®])

DRUG CLASS: Recombinant Human Parathyroid Hormone

BRAND (generic) NAMES: Forteo (teriparatide)
Multi-dose prefilled delivery device (pen) containing 28 daily doses of 20 mcg

FDA-APPROVED INDICATIONS

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture

COVERAGE AUTHORIZATION CRITERIA

Forteo (teriparatide) is covered for the following conditions or situations:

- Treatment of osteoporosis in an adult patient
- Patients who have previously been treated with a bisphosphonate which has failed to treat the patient's osteoporosis, or patients who are unable to receive treatment with a bisphosphonate
- Patients who are not receiving concurrent treatment with a bisphosphonate
- Patients who do not have any of the following conditions where use of teriparatide would not be recommended:
 - Hypercalcemia
 - Paget's disease
 - Prior radiation therapy involving the skeleton
 - Bone metastases or history of skeletal malignancies
 - Metabolic bone disease other than osteoporosis
- Duration of treatment: no longer than 2 years during a patient's lifetime

WARNING: POTENTIAL RISK OF OSTEOSARCOMA

- In rats, 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.
- Forteo should not be prescribed for patients at increased baseline risk for osteosarcoma (e.g., 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).

WARNINGS AND PRECAUTIONS:

- Patients with Paget's disease of bone, pediatric and young adult patients with open epiphyses, and patients with prior external beam or implant radiation involving the skeleton: Should not be treated with Forteo.
- Treatment duration: Use of Forteo for more than 2 years during a patient's lifetime is not recommended.
- Patients with bone metastases, history of skeletal malignancies, metabolic bone diseases other than osteoporosis, or hypercalcemic disorders: Should not be treated with Forteo.
- Laboratory alterations: Forteo may increase serum calcium, urinary calcium, and serum uric acid.
- Urolithiasis: Use with caution in patients with active or recent urolithiasis because of risk of exacerbation.
- Orthostatic hypotension: Transient orthostatic hypotension may occur with initial doses of Forteo.

DOSAGE AND ADMINISTRATION:

- Recommended dose is 20 mcg subcutaneously once a day.
- Administer as a subcutaneous injection into the thigh or abdominal wall.
- Administer initially under circumstances in which the patient can sit or lie down if symptoms of orthostatic hypotension occur.
- Use of the drug for more than 2 years during a patient's lifetime is not recommended.

REFERENCES:

Teriparatide (Forteo) product information. Eli Lilly and Company. Indianapolis, IN. 2010.
<http://pi.lilly.com/us/forteo-pi.pdf>