Abbreviated Prescribing Information

Terifrac

Active Ingredients: Teriparatide [rHu PTH (1-34)] injection (r-DNA origin) 750 mcg / 3 ml.

Indication: For the treatment of Postmenopausal women with osteoporosis who are at high risk for fracture.

Dosage & 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.

Contraindications: Patients with hypersensitivity to Teriparatide or to any of its excipients**.**

Warnings & 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 Teriparatide; Treatment duration: Use of Teriparatide 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 Teriparatide; Laboratory alterations: Teriparatide 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 Teriparatide

Pregnancy & Lactation: Pregnancy category C. The effect of teriparatide treatment on human fetal development has not been studied. Teriparatide is not indicated for use in pregnancy; Nursing mothers: There have been no clinical studies to determine as to whether Teriparatide is secreted into breast milk.

Adverse reactions: Most common adverse reactions (>10%) include: arthralgia, pain, and nausea.