

TeripenTM

Teriparatide injection

Presentation

TeripenTM: Each ml injectable solution contains teriparatide INN 250 mcg. Each cartridge is filled with 2.7 ml to deliver 2.4 ml solution. Each cartridge, pre-assembled into a delivery device (Pen), delivers 20 mcg of teriparatide per dose each day for up to 28 days.

Description

Teripen (teriparatide injection) is a synthetic human parathyroid hormone analog (PTH 1-34). Teripen is supplied as a sterile, colorless, clear, isotonic solution in a glass cartridge which is pre-assembled into a disposable delivery device (pen) for subcutaneous injection.

Indication and Usage

- 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 Glucocorticoid-Induced Osteoporosis at High Risk for Fracture

Dosage and Administration

For all indication: The recommended dose is 20 mcg subcutaneously once a day.

Administration Guideline

- Teripen should be administered as a subcutaneous injection into the thigh or abdominal wall.
- Teripen should be administered initially under circumstances in which the patient can sit or lie down if symptoms of orthostatic hypotension occur
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use if solid particles appear or if the solution is cloudy or colored.
- Patients and caregivers who administer Teripen should receive appropriate training and instruction on the proper use of the Teripen delivery device from a qualified health professional

The safety and efficacy of Teripen have not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years during a patient's lifetime is not recommended.

Side-effects

Teripen is generally well tolerated and safe found in different clinical trials. The most common side-effects are - Pain, Asthenia, Headache, Hypertension, Nausea, Constipation, Diarrhea, Arthralgia, Dizziness, Rhinitis, Increased cough, Pharyngitis, Rash etc. Moreover Teriparatide causes transient increase serum calcium, Urinary Calcium and Uric acid.

Warning and Precaution

- **Osteosarcoma:** Teriparatide should not be prescribed for patients at increased baseline risk of osteosarcoma
- **Bone Metastases and Skeletal Malignancies:** Patients with bone metastases or a history of skeletal malignancies should not be treated with Teripen
- **Metabolic Bone Diseases:** Patients with metabolic bone diseases other than osteoporosis should not be treated with Teripen
- **Hypercalcemia and Hypercalcemic Disorders:** Patients known to have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, should not be treated with Teripen
- **Urolithiasis or Pre-existing Hypercalciuria:** Teripen should be used with caution in patients with active or recent urolithiasis because of the potential to exacerbate this condition.
- **Orthostatic Hypotension:** Teripen should be administered initially under circumstances in which the patient can sit or lie down if symptoms of orthostatic hypotension occur.

Contraindication

Do not use Teripen in patients with Hypersensitivity to teriparatide or to any of its excipients. Reactions have included angioedema and anaphylaxis

Drug Interaction

Teripen has drug interaction with Digoxin, Hydrochlorothiazide and Furosemide. Therefore caution should be exercised during co administration.

Use in specific populations

Pregnancy: There are no available data on Teripen use in pregnant women. Consider discontinuing Teripen when pregnancy is recognized

Lactation: It is not known whether teriparatide is excreted in human milk, affects human milk production, or has effects on the breastfed infant

Pediatric use: The safety and efficacy of Teripen have not been established in any pediatric population.

Over dosage

There is no specific antidote for teriparatide. Treatment of suspected overdose should include discontinuation of Teripen, monitoring of serum calcium and phosphorus, and implementation of appropriate supportive measures, such as hydration

Storage

Store at 2°C to 8°C all time in a refrigerator. Do not freeze. Keep away from light & out of reach of children.

Commercial Pack

TeripenTM: Each box contains one cartridge, pre-assembled into a delivery device (Pen), a leaflet & a user manual.