Teriparatide Injection

PRODUCT	DELIVERY SYSTEM	UNIT SIZE	UNITS / BOX	NDC#
Teriparatide Injection	single-patient-use prefilled delivery device (pen)	560 mcg/2.24 mL	1	0548-2311-00

	WHOLESALER ITEM NUMBERS			
NDC#	CENCORA	CARDINAL	MCKESSON	MORRIS & DICKSON
0548-2311-00	10305803	6098669	3073780	693929

For more information,
PLEASE CALL 1-800-423-4136

AMPHASTAR PHARMACEUTICALS, INC.
11570 Sixth Street, Rancho Cucamonga, CA 91730
www.amphastar.com

See over for full prescribing information

Rx Only
12/25
01-530-01

Teriparatide Injection

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TERIPARATIDE INJECTION safely and effectively.

See full prescribing information for TERIPARATIDE INJECTION.

TERIPARATIDE injection, for subcutaneous use

Initial U.S. Approval: 1987

INDICATIONS AND USAGE

Teriparatide injection is a synthetic parathyroid hormone analog, (PTH 1-34), indicated for:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy

DOSAGE AND ADMINISTRATION

- Recommended dosage is 20 mcg subcutaneously once a day
- Consider supplemental calcium and Vitamin D based on individual patient needs
- Administer as a subcutaneous injection into the thigh or abdominal region
- Administer initially under circumstances in which the patient can sit or lie down if symptoms of orthostatic hypotension occur
- Use of Teriparatide injection for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture

DOSAGE FORMS AND STRENGTHS

Injection: 560 mcg/2.24 mL (250 mcg/mL) in a single-patient-use prefilled delivery device (pen) intended to deliver 28 daily doses of 20 mcg

CONTRAINDICATIONS

- Patients with hypersensitivity to teriparatide or to any of its excipients

WARNINGS AND PRECAUTIONS

- Osteosarcoma: Avoid use in patients with increased risk of osteosarcoma including patients with open epiphyses, metabolic bone diseases including Paget's disease, bone metastases or history of skeletal malignancies, prior external beam or implant radiation therapy involving the skeleton, and hereditary disorders predisposing to osteosarcoma.
- Hypercalcemia and Cutaneous Calcification: Avoid in patients known to have an underlying hypercalcemic disorder Discontinue in patients developing worsening of previously stable cutaneous calcification.
- Risk of Urolithiasis: Consider the risk/benefit in patients with active or recent urolithiasis because of risk of exacerbation
- Orthostatic Hypotension: Transient orthostatic hypotension may occur with initial doses of Teriparatide injection

ADVERSE REACTIONS

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

To report SUSPECTED ADVERSE REACTIONS, contact Amphastar Pharmaceuticals, Inc. at 1-800-423-4136 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

Digoxin: Transient hypercalcemia may predispose patients to digitalis toxicity

USE IN SPECIFIC POPULATIONS

- Pregnancy: Consider discontinuing when pregnancy is recognized
- Lactation: Breastfeeding is not recommended
- Pediatric Use: Safety and effectiveness not established. Avoid use due to increased baseline risk of osteosarcoma