

CinnoPar[®]

Teriparatide
Pen, 600 mcg/2.4 mL



More Dosing Accuracy,
Touch the Patient's Preference

**The First FDA-Approved
Anabolic Drug for Osteoporosis**

Recombinant Human PTH (1-34)



- **CinnoPar®** is recombinant endogenous PTH (1-34) produced by CinnaGen Co.
- **CinnoPar®** is used for treatment of osteoporosis in postmenopausal women, who are at high risk for fractures.
- **CinnoPar®** is used to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fractures.
- **CinnoPar®** is used in men and women with osteoporosis associated with chronic systemic glucocorticoid therapy at high risk for fractures.
- **CinnoPar®** has been produced for SC injection, in 2.4 mL sterile pre-filled pen containing 250 mcg/mL .



CinnoPar®

CinnoPar® is recombinant endogenous parathyroid hormone (PTH), also called rhPTH (1-34). It has an identical sequence to the 34 N-terminal amino acids (the biologically active region) of the human endogenous parathyroid hormone.

Dosage Form and Strength

Sterile pre-filled pen, 2.4 mL, containing 600 mcg of Teriparatide (250 mcg/mL). Each pen provides 30 subcutaneous injections (80 microliters (0.08 mL) or 20 mcg per injection). 20 mcg means 8 clicks on the pen.

Mechanism of Action



The pharmacologic activity of **CinnoPar®**, which is similar to the physiologic activity of PTH, includes stimulating osteoblast function, increasing gastrointestinal calcium absorption, and increasing renal tubular reabsorption of calcium. Treatment with **CinnoPar®** results in increased bone mineral density, bone mass, and strength. In postmenopausal women, teriparatide has been shown to decrease osteoporosis-related fractures.

Indications



- Treatment of osteoporosis in postmenopausal women who are at high risk for fracture (as history of osteoporotic fracture or multiple risk factors for fracture).
- Increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture.
- Treatment of men and women with osteoporosis associated with chronic systemic glucocorticoid therapy with a prednisone dosage of ≥ 5 mg/day (or equivalent) at a high risk for fracture.

Dosing and Administration



- The recommended dose is 20 mcg subcutaneously once a day.
- **CinnoPar**[®] should be administered as a subcutaneous injection into the thigh or abdominal wall.
- **CinnoPar**[®] should be administered initially under circumstances in which the patient may sit or lie down, in the event of orthostasis.
- **CinnoPar**[®] is a clear and colorless liquid. It should not be used if solid particles appear or if the solution is cloudy or colored.

Treatment Duration



Use of **CinnoPar**[®] 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.

Adverse Reactions



>10%:

- **Endocrine & metabolic:** Hypercalcemia (transient increases noted 4 to 6 hours postdose [women 11%; men 6%])
- **Gastrointestinal:** Nausea (9% to 14%)

1% to 10%:

- **Cardiovascular:** Orthostatic hypotension (5%; transient), angina pectoris (3%), syncope (3%)
- **Nervous system:** Dizziness (8%), headache (8%), insomnia (5%), anxiety (4%), depression (4%), vertigo (4%)
- **Endocrine & metabolic:** Hyperuricemia (3%)
- **Gastrointestinal:** Gastritis (7%), dyspepsia (5%), vomiting (3%)
- **Immunologic:** Antibody development (3% of women in long-term treatment; hypersensitivity reactions or decreased efficacy were not associated in preclinical trials)
- **Infection:** Herpes zoster (3%)
- **Neuromuscular & skeletal:** Arthralgia (10%), asthenia (9%), lower limb cramp (3%)
- **Respiratory:** Rhinitis (10%), pharyngitis (6%), dyspnea (4% to 6%; including acute dyspnea), pneumonia (3% to 6%)

Use in specific populations



Pregnancy:

Adverse events were observed in animal reproduction studies. Consider discontinuing treatment once pregnancy is recognized.

Breastfeeding:

It is not known if teriparatide is present in breast milk. It is recommended to avoid using in patients who are breastfeeding.

Pediatrics:

CinnoPar[®] should not be used in pediatric and young adult patients with open epiphyses.

Contraindications



Do not use **CinnoPar®** in patients with hypersensitivity (angioedema and anaphylaxis) to Teriparatide or to any of its excipients.

Warnings and Precautions



- Patients with Paget 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 **CinnoPar®**.
- Patients with bone metastases, history of skeletal malignancies, metabolic bone diseases other than osteoporosis, or hypercalcemic disorders: Should not be treated with **CinnoPar®**.
- **Hypercalcemia:** Use with caution in patients with hypercalcemia; may increase or exacerbate hypercalcemia. Avoid use in patients with known or history of hypercalcemia disorder (eg, primary hyperparathyroidism).
- **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 **CinnoPar®**, which is usually resolved without treatment within a few minutes to a few hours.

Monitoring Parameters



- Orthostatic hypotension
- Serum calcium (draw at least 16 hours after teriparatide dose)
- Urinary calcium (in active urolithiasis or preexisting hypercalciuria)
- Bone mineral density (BMD) (at baseline and 1 to 2 years following initiation of therapy)
- Biochemical markers of bone turnover if needed to assess treatment response (at baseline, 3 months, and 6 months)

Storage and Handling



CinnoPar® pen should:

- be stored in the refrigerator at 2°C to 8°C. During the use period, time out of the refrigerator should be minimized; the dose may be delivered immediately following removal from refrigerator.
- not be frozen.
- not be used after expiry date stated on the label and packaging.
- be thrown away after 30 days, even if it has medicine in it.

References:

1. Teriparatide drug information- UpToDate [January 2023]
2. CinnoPar® Leaflet