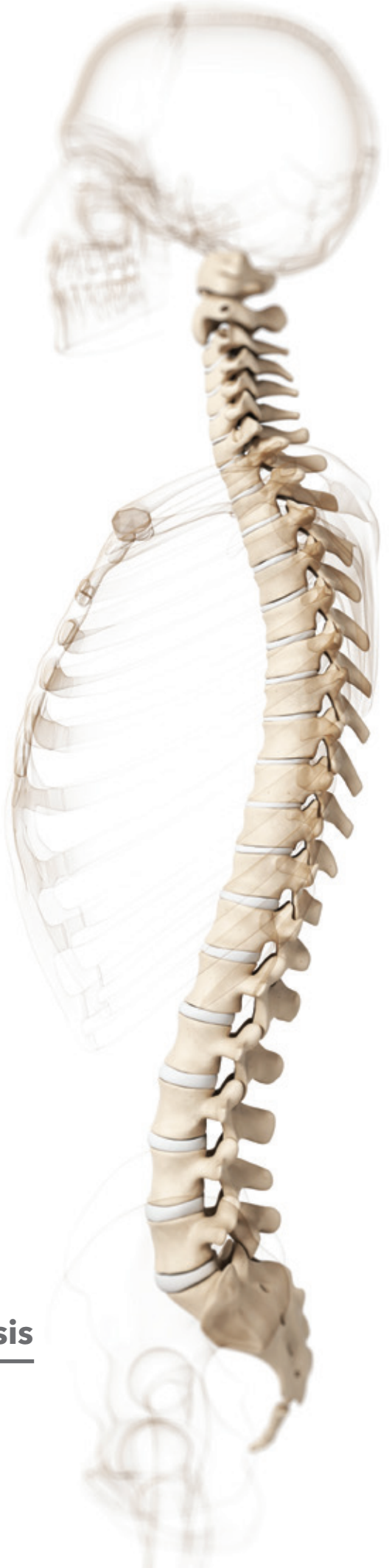
Cinn-O-Par®
Teriparatide



More Dosing Accuracy, Touch the Patient Preference

The Only FDA-Approved Anabolic Drug for Osteoporosis

Recombinant Human PTH (1-34)

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The Only FDA-Approved Anabolic Drug for Osteoporosis

Recombinant Human PTH (1-34)

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

CinnoPar®

CinnoPar® is recombinant human parathyroid hormone (PTH), and is also called rhPTH (1-34). It has an identical sequence to the 34 N-terminal amino acids (the biologically active region) of the 84-amino acid human parathyroid hormone.
CinnoPar® (teriparatide) has a molecular weight of 4117.8 D and its amino acid sequence is shown below:

CinnoPar® is manufactured using a strain of *Escherichia coli* modified by recombinant DNA technology.

Indications

- Treatment of osteoporosis in postmenopausal women who are at high risk 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 sustained systemic glucocorticoid therapy at high risk for fracture.
  High fracture risk is defined as a value for BMD more than 2.5 SD below the young adult female reference mean in the presence of one or more fragility fractures.

Mechanism of Action

The skeletal effects of Teriparatide depend upon the pattern of systemic exposure. Once-daily administration of **CinnoPar®** stimulates new bone formation on trabecular and cortical (periosteal and/ or endosteal) bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity.

Administration

- **CinnoPar®** should be administered as a subcutaneous injection into the thigh or abdominal wall. There are no data available on the safety or efficacy of intravenous or intramuscular injection of **CinnoPar®**.
- **CinnoPar®** 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, whenever solution and container permit. **CinnoPar®** is a clear and colorless liquid. It should not be used if solid particles appear or if the solution is cloudy or colored.
- Patients and caregivers who administer **CinnoPar®** should receive appropriate training and instruction on the proper use of the CinnoPar® delivery device from a qualified health professional.

Treatment Duration

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

Dosage of administration

The recommended dose is 20 mcg subcutaneously once a day.

Dosage Form and Strength

CinnoPar® has been produced in 2.4 ml pen containing 600 mcg of Teriparatide (250 mcg/ ml). Each pen provides 30 subcutaneous injections (80 microliters (0.08 ml) or 20 mcg per injection). 0.08 ml means 8 units on the pen.

Side Effects

>10%:

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

1% to 10%:

- Cardiovascular: Orthostatic hypotension (5%; transient), angina pectoris (3%), syncope (3%)
- Central nervous system: Dizziness (8%), headache (8%), insomnia (5%), anxiety (4%), depression (4%), vertigo (4%)
- Endocrine & metabolic: Hyperuricemia (3%)
- Gastrointestinal: Nausea (9% to 14%), 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%), weakness (9%), leg cramps (3%)
- Respiratory: Rhinitis (10%), pharyngitis (6%), dyspnea (4% to 6%), pneumonia (3% to 6%)

Drug interactions

Digoxin: Use **CinnoPar®** with caution in patients receiving digoxin. Transient hypercalcemia may predispose patients to digitalis toxicity.

Use in specific populations

Pregnancy:
Pregnancy risk factor: C

Nursing Mothers:
Discontinue nursing or **CinnoPar®**, taking into account the importance of treatment to the mother.

Pediatrics:
CinnoPar® should not be used in pediatric and young adult patients with open epiphysis due to increased baseline risk of osteosarcoma.

Geriatric:
No age-related differences in Teriparatide pharmacokinetics were detected (range 31 to 85 years).

Contraindications

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

Warnings and Precautions

- Patients with Paget's disease of bone, pediatric and young adult patients with open epiphysis, and patients with prior external beam or implant radiation involving the skeleton:

Should not be treated with **CinnoPar®**

- **Treatment duration:**

Use of **CinnoPar®** 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 **CinnoPar®**.

- **Laboratory alterations:**

CinnoPar® 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 **CinnoPar®**.

Storage and Handling

- The **CinnoPar®** Pen should be stored under refrigeration at 2 to 8° C (36 to 46° F) and protected from light at all times.
- During the use period, time out of the refrigerator should be minimized; the dose may be delivered immediately following removal from the refrigerator.
- Do not freeze. Do not use **CinnoPar®** if it has been frozen.

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