

What is CinnoPar®?

CinnoPar® is a recombinant human parathyroid hormone analog produced by Singapore Biotech. CinnoPar® is a prescription drug which is like natural hormone secreted by parathyroid glands called parathyroid hormone or PTH. CinnoPar® stimulates bone formation, increases bone mineral density and bone strength. CinnoPar® can lessen the number of fractures of the spine and other bones in postmenopausal women with osteoporosis.

CinnoPar® is used in both men and postmenopausal women with osteoporosis who are at high risk for having fractures.

CinnoPar® can be used by people who have had a fracture related to osteoporosis, or who have multiple risk factors for fracture, or who cannot use other osteoporosis treatments.

Also, CinnoPar® is indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

It is not known if CinnoPar® is safe and effective in children. CinnoPar® should not be used in children and young adults whose bones are still growing.

Who should not use CinnoPar®?

Do not use CinnoPar® if you:

- Are allergic to teriparatide or any components of CinnoPar® formulation.
- Have Paget's disease.
- Have unexplained high blood levels of alkaline phosphatase, which means you might have Paget's disease or other bone disease.
- Are a child or young adult whose bones are still growing.
- Have ever been diagnosed with bone cancer or other cancers that have spread (metastasized) to your bones.
- Have had radiation therapy involving the skeleton.
- Have certain bone diseases. If you have a bone disease, tell your doctor.
- Have or had too much calcium in your blood (hypercalcemia).

CinnoPar® should not be used to prevent osteoporosis. CinnoPar® should be used to treat osteoporotic patients who are considered to be at high risk for fracture.

What should I tell my healthcare provider before taking CinnoPar®?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have one of the conditions listed in the section "Who should not use CinnoPar®?"
 - Have trouble injecting yourself and do not have someone who can help you.
 - Have or had kidney diseases including kidney stones.
 - Have hepatic impairment.
 - Have cardiovascular diseases.
 - Have hyperparathyroidism.
 - Are pregnant or thinking about becoming pregnant. It is not known if CinnoPar® will harm your unborn baby.
 - Are breast-feeding or thinking about breast-feeding. It is not known if CinnoPar® is excreted into breast milk. You should discontinue nursing while taking CinnoPar®.
- Before taking CinnoPar® tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Your healthcare provider needs this information to keep you from taking CinnoPar® with other medicines that may harm you.
- Especially tell your doctor if you take medicines that contain digoxin (for example, Digoxin, Lanoxicaps, Lanoxin).

How should I use CinnoPar®?

- It is not recommended to use CinnoPar® for more than two years.
- Administer the drug daily with subcutaneous injection.
- The daily dosing of the drug is 20 mcg which is equal to 0.08 cc.
- 0.08 cc means 8 units on the Pen. For this purpose, rotate the dose dialer until "8" aligns with the pointer in the dose window to set dose to 8 units.
- Do not transfer the medicine from the CinnoPar® delivery device to a syringe. This can result in taking the wrong dose of CinnoPar®.
- CinnoPar® should look clear and colorless. Do not use CinnoPar® if it has particles in it, or if it is cloudy or colored.
- After each use, safely remove the needle, recap the delivery device, and put it back in the refrigerator right away.
- You can take CinnoPar® with or without food or drink.
- You can take CinnoPar® at any time of the day. To help you remember to take CinnoPar®, take it at about the same time each day.
- If you forget or cannot take CinnoPar® at your usual time, take it as soon as you can on that day. Do not take more than one injection in the same day.
- **Do not inject all the medicine in the CinnoPar® delivery device at any one time.** If you take more CinnoPar® than prescribed, call your healthcare provider.

If you take too much CinnoPar®, you may have nausea, vomiting, weakness, or dizziness.

- Throw away CinnoPar® delivery device after 30 days, even if it still contains medicine.
- The best injection sites are your thigh or abdomen.
- The injection site should not be constant.

What are the possible side effects of CinnoPar®?

Most side effects are mild and include:

- Nausea.
- Vertigo and dizziness
- Orthostatic Hypotension. Some patient may feel lightheaded or have palpitation right after the first few doses. This usually begin within 4 hours of taking CinnoPar® and resolves within a few hours. **For the first few doses, take your injections of CinnoPar® in a place where you can sit or lie down right away if you get these symptoms.** If your symptoms get worse or do not go away, stop taking CinnoPar® and call your healthcare provider.
- Leg cramps.
- Joint aches.
- Increased calcium in your blood (Hypercalcemia). Tell your healthcare provider if you have persistent nausea, vomiting, constipation, low energy, or muscle weakness. These may be the symptoms of hypercalcemia.
- Injection site reactions including redness, swelling, pain, itching, a few drops of blood, and bruising.

These are not all the possible side effects of CinnoPar®. Tell your healthcare provider if you have any side effect that bothers you or that does not resolve. Call your doctor for medical advice about side effects.

Your healthcare provider may take samples of blood and urine during treatment to check your response to CinnoPar®. Also, your healthcare provider may ask you to have follow up tests of bone mineral density.

How should I store CinnoPar®?

- Keep your CinnoPar® pen in the refrigerator at 2 to 8 °C or 36 to 46 °F
- Do not freeze the CinnoPar® pen. Do not use CinnoPar® if it has been frozen.
- Do not use CinnoPar® after the expiration date printed on the label of pen and packaging.
- Throw away the CinnoPar® pen after 30 days even if it has medicine in it.
- Keep CinnoPar® like all medicines out of the reach of children.

Points to be noticed while taking CinnoPar®

This Medication Guide summarizes the most important information about CinnoPar®, but medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

- Do not use CinnoPar® for a condition for which it was not prescribed.
- Do not give CinnoPar® to other people, even if they have the same condition you have.

If you would like to have more information, talk with your healthcare provider or your pharmacist.

What are the ingredients in CinnoPar®?

Active ingredient: Teriparatide

Inactive ingredients: glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, and water for injection. In addition, hydrochloric acid solution 10% and/or sodium hydroxide solution 10% may have been added to adjust the product to pH 4.

What is Osteoporosis?

Osteoporosis is a disease in which the bones become brittle and weak, increasing the chance of having a fracture. Osteoporosis usually causes no symptoms until a fracture happens. The most common fractures are in the spine (backbone). They can shorten height, even without causing pain. Over time, the spine can become curved or deformed and the body bent over. Fractures from osteoporosis can also happen in almost any bone in the body, for example, the wrist, rib, or hip. Once you have had a fracture, the chance for more fractures greatly increases.

The following risk factors increase your chance of getting fractures from osteoporosis:

1. Prior bone fracture from osteoporosis.
2. Very low bone mineral density (BMD).
3. Frequent falls.
4. Limited movement, such as using a wheelchair.
5. Medical conditions likely to cause bone loss, such as some kinds of arthritis.
6. Medicines that may cause bone loss, for example: Anticonvulsant (such as phenytoin), Anticoagulant (such as heparin), steroids, and high doses of vitamin A.