

This Patient leaflet was formatted according to Ministry of Health guidelines. It was reviewed and approved by the Ministry of Health in November 2018

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The dispensing of this medicine requires a doctor's prescription

Cinacalcet Taro film-coated tablets 30 mg, 60 mg, 90 mg

Active ingredient and its quantity

Each film-coated tablet contains 30 mg, 60 mg or 90 mg of cinacalcet (as hydrochloride).

Inactive ingredients and allergens: see Section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about the medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is not for use in children and adolescents under 18 years of age.

1. What is this medicine intended for?

Cinacalcet Taro is used:

- to treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products.
- to reduce high levels of calcium in the blood (hypercalcemia) in patients with parathyroid cancer.
- to reduce high levels of calcium in the blood (hypercalcemia) in patients with primary hyperparathyroidism when removal of the gland is not possible.

Therapeutic group: Cinacalcet Taro is a calcimimetic agent.

Cinacalcet Taro works by controlling the levels of parathyroid hormone (PTH), calcium, and phosphorous in your body. It is used to treat problems with organs called parathyroid glands. The parathyroids are four small glands in the neck, near the thyroid gland, that produce parathyroid hormone (PTH).

In primary and secondary hyperparathyroidism too much PTH is produced by the parathyroid glands. 'Primary' means that the hyperparathyroidism is not caused by any other condition and 'secondary' means that the hyperparathyroidism is caused by another condition, e.g., kidney disease. Both primary and secondary hyperparathyroidism can cause the loss of calcium in the bones, which can lead to bone pain and fractures, problems with blood and heart vessels, kidney stones, mental illness and coma.

2. Before using this medicine

X Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (for a list of inactive ingredients, see Section 6).

! Special warnings regarding use of this medicine

Talk to your doctor before taking Cinacalcet Taro.

! Before you start taking Cinacalcet Taro, tell your doctor if you have, or have ever had:

- seizures** (fits or convulsions). The risk of having seizures is higher if you have had them before;
- liver problems;**
- heart failure.**

Life threatening events and fatal outcomes associated with low calcium levels (hypocalcemia) have been reported in patients treated with Cinacalcet Taro. Low calcium levels can have an effect on your heart rhythm. Tell your doctor if you experience an unusually fast or pounding heart beat, if you have heart rhythm problems, or if you take medicines known to cause heart rhythm problems, while taking Cinacalcet Taro.

For additional information see Section 4 'Side Effects'.

! Smoking

During treatment with Cinacalcet Taro, tell your doctor:
If you start or stop smoking, as this may affect the way Cinacalcet Taro works.

! Children and adolescents

Children under the age of 18 must not take Cinacalcet Taro.

! Tests and follow up

Your doctor will request regular blood samples during treatment to monitor your progress and will adjust your dose if necessary.

! Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

Medicines that can affect the activity of Cinacalcet Taro:

- medicines used to treat **skin and fungal infections** (ketoconazole, itraconazole and voriconazole);
- medicines used to treat **bacterial infections** (telithromycin, rifampicin and ciprofloxacin);
- a medicine used to treat **HIV** infection and AIDS (ritonavir);
- a medicine used to treat **depression** (fluvoxamine).

Cinacalcet Taro may affect the activity of the following medicines:

- medicines used to treat **depression** (amitriptyline, desipramine, nortriptyline and clomipramine);
- a medicine used to relieve **cough** (dextromethorphan);
- medicines used to treat **changes in heart rate** (flecainide and propafenone);
- a medicine used to treat **high blood pressure** (metoprolol).

¶ Taking Cinacalcet Taro and food

Cinacalcet Taro should be taken with or shortly after food.

¶ Pregnancy and breastfeeding

Consult your doctor or pharmacist before using this medicine.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Cinacalcet Taro has not been tested in pregnant women. In case of pregnancy, your doctor may decide to modify your treatment, as Cinacalcet Taro might harm the unborn baby.

It is not known whether Cinacalcet Taro passes into breast milk. Your doctor will discuss with you if you should discontinue either breastfeeding or treatment with Cinacalcet Taro.

¶ Driving and using machines

There are no studies of the effect on ability to drive or operate machines.

Dizziness and seizures have been reported by patients taking Cinacalcet Taro. If you experience these effects, your ability to drive or operate machinery may be affected.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine. The recommended dose is usually:

If you are being treated for secondary hyperparathyroidism

The usual starting dose for Cinacalcet Taro is 30 mg (one tablet of 30 mg) once per day.

If you are being treated for parathyroid cancer or primary hyperparathyroidism

The usual starting dose for Cinacalcet Taro is 30 mg (one tablet of 30 mg) twice per day.

Do not exceed the recommended dose

Cinacalcet Taro should be taken by mouth, with or shortly after food. Take the tablets whole and do not split them.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Possible signs of overdose include numbness or tingling around the mouth, muscle aches or cramps and seizures.

If you forget to take the medicine, do not take a double dose to make up for a forgotten dose.

If you forget to take a dose of Cinacalcet Taro, take your next dose as usual.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Even if your health improves, do not stop taking this medicine without consulting your doctor first.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, using Cinacalcet Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor immediately if you experience any of the following side effects:

- numbness or tingling around the mouth
- muscle aches
- cramps
- seizures.

These may be signs that your calcium levels are too low (hypocalcemia).

Additional side effects

Very common side effects: may affect more than 1 in 10 people

- nausea and vomiting, these side effects are normally quite mild and do not last for long.

Common side effects: may affect up to 1 in 10 people

- dizziness
- numbness or tingling sensation (paresthesia)
- loss (anorexia) or decrease of appetite
- muscle pain (myalgia)
- weakness (asthenia)
- rash
- reduced testosterone levels

- high potassium levels in the blood (hyperkalemia)
- allergic reactions (hypersensitivity)
- headache
- seizures (convulsions or fits)
- low blood pressure (hypotension)
- upper respiratory infection
- breathing difficulties (dyspnea)
- cough
- indigestion (dyspepsia)
- diarrhea
- abdominal pain, upper abdominal pain
- constipation
- muscle spasms
- back pain
- low calcium levels in the blood (hypocalcemia).

Unknown frequency: frequency cannot be estimated from available data

- hives (urticaria)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulties in swallowing or breathing (angioedema)
- unusually fast or pounding heart beat which may be associated with low levels of calcium in your blood (QT prolongation and ventricular arrhythmia secondary to blood hypocalcemia).

After taking Cinacalcet Taro, a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension).

Children and adolescents

The use of Cinacalcet Taro in children and adolescents has not been established. A fatal outcome was reported in an adolescent clinical-trial patient with very low calcium levels in the blood (hypocalcemia).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffe ctMedic@moh.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) stated on the package and blister tray. The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in the original package.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient this medicine also contains:

Pregelatinized starch, microcrystalline cellulose, povidone, crospovidone, magnesium stearate, colloidal anhydrous silica.

Tablets are coated with:

Polyvinyl alcohol-partially hydrolyzed, titanium dioxide (e171), macrogol, talc, FD&C blue #2/ indigo carmine aluminum lake (E132), iron oxide yellow (E172).

What the medicine looks like and what are the contents of the package:

Cinacalcet Taro is a light green film-coated tablet. Tablets are oval and are marked "30", "60" or "90" on one side and "CC9C" on the other side.

Cinacalcet Taro is available in blister trays of 30 mg, 60 mg or 90 mg film-coated tablets. Each blister pack contains 14, 28 or 84 tablets in a carton.

Not all pack sizes may be available.

Registration holder name and address:

Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

Manufacturer name and address:

Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

This leaflet was reviewed and approved by the Ministry of Health in: November 2018

Registration number of the medicine in the Ministry of Health National Drug Registry:

Cinacalcet Taro 30 mg 160.90.35048

Cinacalcet Taro 60 mg 160.91.35049

Cinacalcet Taro 90 mg 160.92.35050