

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Cinacalcet-Trima

30 mg, 60 mg, 90 mg

Film-coated tablets

Active ingredient:
Each tablet contains: 30 mg, 60 mg, 90 mg cinacalcet (as hydrochloride).

For information about inactive ingredients and allergens in this medicine, please see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.
This medicine is not intended for children under 18 years old.

1. What is this medicine intended for?

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

Therapeutic group:
This medicine regulates the levels of calcium and has anti-parathyroid activity. It is used to treat diseases caused by impaired function of the organs called parathyroid glands.

2. Before using this medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient cinacalcet or to any of the other ingredients in this medicine (listed in section 6).

Special warnings about using this medicine:
Consult a doctor, pharmacist, or nurse before you take Cinacalcet-Trima.

Before you start treatment with Cinacalcet-Trima, tell your doctor if:
you have or have ever had:
• epileptic seizures (convulsions or spasms). The risk of having these seizures is higher in patients who have had seizures before.
• liver problems.
• heart failure.

Life threatening conditions and cases of death associated with low calcium levels in the blood (hypocalcaemia) have been reported in patients taking cinacalcet.

Low calcium levels can affect your heart rhythm. Tell your doctor if you experience an unusually fast or pounding heartbeat, if you have heart rhythm problems, or if you take medicines known to cause heart rhythm problems, while taking Cinacalcet-Trima.
For additional information, see section 4, 'Side effects'.

Smoking

During treatment with Cinacalcet-Trima, tell your doctor:
• if you start or stop smoking, as this may affect the way this medicine works.

Children and adolescents

This medicine is not intended for children under 18 years old.

Tests and follow-up

While you are taking this medicine, your doctor will refer you for routine blood tests to check your reaction to the medicine and will adjust your dose as necessary to control your calcium levels.

Interactions with other medicines

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 such as these which can affect how Cinacalcet-Trima works:
- medicines used to treat **skin and fungal infections** (such as ketoconazole, itraconazole and voriconazole)
 - medicines used to treat **bacterial infections** (such as telithromycin, rifampicin and ciprofloxacin)
 - medicines used to treat **HIV** infection and **AIDS** (such as ritonavir)
 - medicines used to treat **depression** (fluvoxamine).

Cinacalcet-Trima may affect how medicines such as the following work:

- medicines used to treat **depression** (such as amitriptyline, desipramine, nortriptyline, and clomipramine)

- medicines used to treat **heart rhythm disorders** (such as flecainide and propafenone)
- medicines used to treat **high blood pressure** (such as metoprolol).

Using this medicine and food:

Take this medicine with or immediately after a meal.

Pregnancy and breastfeeding:

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 has not been tested in pregnant women. In case of pregnancy, your doctor may decide to modify your treatment, as the medicine might harm your unborn baby.
It is not known whether cinacalcet passes into breast milk. Your doctor will discuss with you if you should stop either breastfeeding or treatment with Cinacalcet-Trima.

Driving and using machines:

The effect of this medicine on ability to drive and use machines has not been tested. Dizziness and convulsions have been reported by patients taking this medicine. If you experience either of these side effects your ability to drive or operate machine may be impaired.

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 dosage is usually:

If you are being treated for secondary hyperparathyroidism:

The usual starting dose for Cinacalcet-Trima is 30 mg (one tablet) once a day.
If you are being treated for parathyroid cancer or primary hyperparathyroidism:
The usual starting dose for Cinacalcet-Trima is 30 mg (one tablet) twice a day.

Do not exceed the recommended dose.

How to use this medicine

- Swallow the medicine with water
- Take this medicine with or immediately after a meal

Crushing/splitting/chewing

- There is no score line on the tablets, so do not split them.
- There is no information about crushing/chewing the tablets.

If you have accidentally taken a higher dose,
you may experience: numbness or tingling around the mouth, muscle pain, or cramps and convulsions. If you have taken an overdose, 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.

If you forget to take this medicine at the scheduled time, do not take a double dose; take the next dose at the usual time.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine: If you want to stop taking this medicine, consult your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose every 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 with all medicines, using Cinacalcet-Trima 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 the following side effects:

- numbness or tingling around the mouth
- muscle pain
- muscle cramps
- convulsions.

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 patients):
• nausea and vomiting. These side effects are usually quite mild and do not last for long.

Common side effects (may affect 1 in 10 patients):

- dizziness
- numbness or tingling sensation on the skin (paraesthesia)
- loss of appetite or reduced appetite
- muscle pain
- weakness
- rash
- reduced testosterone levels
- high potassium levels in the blood (hyperkalemia)
- allergic reaction (hypersensitivity)
- headache

- spasms/convulsions
- low blood pressure
- upper respiratory infection
- breathing difficulties (dyspnea)
- cough
- indigestion (dyspepsia)
- diarrhea
- abdominal pain, pain in the top part of the abdomen
- constipation
- muscle cramps
- back pain
- low calcium levels in the blood (hypocalcemia).

Possible side effects of unknown frequency:

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

A very small number of patients with heart failure had worsening of their condition and/or low blood pressure after taking cinacalcet.

Children and adolescents

Use of cinacalcet in children and adolescents has not been established. There is a report of the death of a patient with very low levels of calcium in the blood (hypocalcemia) during a clinical trial in adolescents.

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 Drug Treatment' 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://sideeffects.health.gov.il>

You can also report by email at: safety@trima.co.il

5. How to store the medicine?

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

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- instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/blister tray. The expiry date refers to the last day of that month.
- Storage conditions**
- Store below 25°C. Store in the original package.
 - Do not throw away any medicine 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:**
microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, HPMC, titanium dioxide, polyethylene glycol 400, FD&C Blue No.1 aluminium lake, D&C yellow No.10 aluminium lake, erythrosine aluminium lake, FD&C Blue No. 2 aluminium lake.
- **What the medicine looks like and contents of the pack**
Cinacalcet-Trima 30 mg: round, light green, film-coated tablet
Cinacalcet-Trima 60 mg: round, light green, film-coated tablet.
Cinacalcet-Trima 90 mg: oblong, light green, film-coated tablet.
Each pack contains 28 tablets packaged in blisters.
- **Manufacturer and registration holder:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in November 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Cinacalcet-Trima 30 mg: 154-44-34241-00
Cinacalcet-Trima 60 mg: 154-45-34240-00
Cinacalcet-Trima 90 mg: 154-46-34209-00



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