

CINACRED 30 (Cinacalcet Tablets 30 mg)

CINACRED 60 (Cinacalcet Tablets 60 mg)

CINACRED 90 (Cinacalcet Tablets 90 mg)

Cinacalcet (30mg, 60mg, 90mg)

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What CINACRED is used for

Cinacalcet is used in adults:

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

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.

How CINACRED works

Cinacalcet 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).

Before you take CINACRED

-When you must not take it

-Do not take Cinacalcet if you are allergic to cinacalcet or any of the other ingredients of this medicine
-Do not take Cinacalcet if you have low levels of calcium in your blood. Your doctor will monitor your blood calcium levels.

-Before you start to take it

Talk to your doctor, pharmacist or nurse before taking cinacalcet.

Before you start taking cinacalcet, 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.

Cinacalcet reduces calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in adults treated with cinacalcet.

Please tell your doctor if you experience any of the following which may be signs of low calcium levels: spasms, twitches, or cramps in your muscles, or numbness or tingling in your fingers, toes or around your mouth or seizures, confusion or loss of consciousness while being treated with cinacalcet.

Low calcium levels can have an effect on 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. For additional information see section "Side Effects"

During treatment with cinacalcet, tell your doctor:

- if you start or stop smoking, as this may affect the way cinacalcet works.

Children and adolescents

Children under the age of 18 with parathyroid cancer or primary hyperparathyroidism must not take cinacalcet.

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with cinacalcet and during treatment with cinacalcet. You should inform your doctor if you experience any of the signs of low calcium levels as described above. It is important that you take your dose of cinacalcet as advised by your doctor.

Pregnancy, breastfeeding and fertility

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 cinacalcet might harm the unborn baby. It is not known whether cinacalcet is excreted in human milk. Your doctor will discuss with you if you should discontinue either breast-feeding or treatment with cinacalcet.

Driving and using machines

Dizziness and seizures have been reported by patients taking cinacalcet. If you experience these side effects, do not drive or operate machines.

Cinacalcet tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines particularly etelcalcetide or any other medicines that lower the level of calcium in your blood. You should not receive cinacalcet together with etelcalcetide.

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Tell your doctor if you are taking the following medicines. Medicines such as these can affect how cinacalcet works:

- 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 may affect how medicines such as the following work:

- 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).

Cinacalcet with food and drink

Cinacalcet should be taken with or shortly after food.

How to take CINACRED

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure. Your doctor will tell you how much Cinacalcet you must take. Your doctor will take regular blood samples during treatment to monitor your progress and will adjust your dose if necessary.

How much to take

If you are being treated for secondary hyperparathyroidism

The usual starting dose for cinacalcet in adults is 30 mg (one tablet) once per day.

If you are being treated for parathyroid cancer or primary hyperparathyroidism

The usual starting dose for cinacalcet in adults is 30 mg (one tablet) twice per day

-When to take it

Cinacalcet must be taken orally, with or shortly after food. The tablets must be taken whole and are not to be chewed, crushed or divided.

-How long to take it

Your doctor will advise how long you should take CINACRED.

-If you forget to take it

Do not take a double dose to make up for a forgotten dose. If you have forgotten a dose of Cinacalcet, you should take your next dose as normal.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

-If you have taken too much (overdose)

If you take more Cinacalcet than you should you must contact your doctor immediately. Possible signs of overdose include numbness or tingling around the mouth, muscle aches or cramps and seizures.

While you are taking CINACRED

-Things you must do

Always follow your doctor's instructions carefully.

-Things you must not do

- Do not give CINACRED to anyone else, even if they have the same condition as you.
- Do not use CINACRED to treat any other medical complaints unless your doctor tells you to.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Please tell your doctor immediately:

- If you start to get numbness or tingling around the mouth, muscle aches or cramps and seizures. These may be signs that your calcium levels are too low (hypocalcaemia).

- If you experience swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema).

Very common: 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: may affect up to 1 in 10 people

- dizziness
- numbness or tingling sensation (paraesthesia)
- loss (anorexia) or decrease of appetite
- muscle pain (myalgia)
- weakness (asthenia)
- rash
- reduced testosterone levels
- high potassium levels in the blood (hyperkalaemia)
- allergic reactions (hypersensitivity)
- headache
- seizures (convulsions or fits)
- low blood pressure (hypotension)
- upper respiratory infection
- breathing difficulties (dyspnoea)
- cough
- indigestion (dyspepsia)
- diarrhoea
- abdominal pain, abdominal pain – upper
- constipation
- muscle spasms
- back pain
- low calcium levels in the blood (hypocalcaemia).

Not known: frequency cannot be estimated from available data

- hives (urticaria)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty 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 hypocalcaemia).

After taking cinacalcet a very small

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number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of CINACRED

-Storage

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Store below 30°C

-Disposal

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.

Product description

What it looks like

Cinacalcet tablets are light green film-coated tablets. They are oval-shaped and have “30”, “60” or “90” marked on one side and “C” on the other side. Pack Size: Two blisters containing 14 tablets each are packed into an outer carton with a pack insert.

Ingredients

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

Inactive ingredients: starch
pregelatinized, cellulose
microcrystalline, povidone
Crospovidone, silica colloidal
anhydrous, magnesium stearate.
• The tablets are coated with:

lactose monohydrate
hypromellose (E464), titanium dioxide (E171), triacetin, indigo carmine (E132), iron oxide yellow (E172).

MAL number:

MAL24096015AZ - CINACRED 90

MAL24096014AZ - CINACRED 60

MAL24096013AZ - CINACRED 30

Manufacturer

Dr. Reddy's Laboratories Limited.,
Formulation Tech Ops – II
Survey No 2p,43,44p,45p,46p,53,54 &
83, Bachupally Village,
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Product Registration Holder

Dr. Reddy's Laboratories Malaysia
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