

Package leaflet: Information for the patient

Cinacalcet Pharmazac 30 mg, filmomhulde tabletten **Cinacalcet Pharmazac 60 mg, filmomhulde tabletten** **Cinacalcet Pharmazac 90 mg, filmomhulde tabletten** Cinacalcet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cinacalcet Pharmazac is and what it is used for
2. What you need to know before you take Cinacalcet Pharmazac
3. How to take Cinacalcet Pharmazac
4. Possible side effects
5. How to store Cinacalcet Pharmazac
6. Contents of the pack and other information

1 What Cinacalcet Pharmazac is and what it is used for

Cinacalcet Pharmazac 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).

Cinacalcet Pharmazac is used in adults:

- 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 (hypercalcaemia) in patients with parathyroid cancer.
- to reduce high levels of calcium in the blood (hypercalcaemia) in patients with primary hyperparathyroidism when removal of the gland is not possible.

Cinacalcet Pharmazac is used in children aged 3 years to less than 18 years of age:

- to treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products, whose condition is not controlled with other treatments.

In primary and secondary hyperparathyroidism too much PTH is produced by the parathyroids 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 What you need to know before you take Cinacalcet Pharmazac

Do not take Cinacalcet Pharmazac

- if you are **allergic to cinacalcet or any of the other ingredients** of this medicine (listed in section 6).
- if you have low levels of calcium in your blood. Your doctor will monitor your blood calcium levels.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cinacalcet Pharmazac

Before you start taking Cinacalcet Pharmazac, 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 Pharmazac reduces calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in patients 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 Pharmazac.

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 Pharmazac.

For additional information see section 4.

During treatment with Cinacalcet Pharmazac, tell your doctor:

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

Children and adolescents

Children under the age of 18 with parathyroid cancer or primary hyperparathyroidism must not take Cinacalcet Pharmazac

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium

levels before starting treatment with Cinacalcet Pharmazac and during treatment with Cinacalcet Pharmazac. 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.

Other medicines and Cinacalcet Pharmazac

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 Pharmazac together with etelcalcetide.

Tell your doctor if you are taking the following medicines

Medicines such as these can affect how Cinacalcet Pharmazac 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 Pharmazac 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 Pharmazac with food and drink

Cinacalcet Pharmazac should be taken with or shortly after food.

Pregnancy, breast-feeding and fertility

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

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

It is not known whether Cinacalcet Pharmazac is excreted in human milk. Your doctor will discuss with you if you should discontinue either breast-feeding or treatment with Cinacalcet Pharmazac.

Driving and using machines

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

3 How to take Cinacalcet Pharmazac

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 Pharmazac you must take.

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

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

If you are being treated for secondary hyperparathyroidism

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

The usual starting dose of Cinacalcet Pharmazac for children aged 3 years to less than 18 years of age is no more than 0.20 mg/kg of body weight daily.

If you are being treated for parathyroid cancer or primary hyperparathyroidism

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

If you take more Cinacalcet Pharmazac than you should

If you take more Cinacalcet Pharmazac 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.

If you forget to take Cinacalcet Pharmazac

Do not take a double dose to make up for a forgotten dose.

If you have forgotten a dose of Cinacalcet Pharmazac, 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.

4 Possible 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 Pharmazac a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cinacalcet Pharmazac

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.

This medicine does not require any special storage conditions.

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 Contents of the pack and other information

What Cinacalcet Pharmazac contains

- The active substance is cinacalcet. Each tablet contains 30 mg 60 mg 90 mg of cinacalcet (as hydrochloride) .
- The other ingredients are: starch, pregelatinized (maize), cellulose, microcrystalline (E460), povidone (K-29/32), crospovidone (type A and B), magnesium stearate (E572), silica, colloidal anhydrous (tablet core); polyvinyl alcohol-partially hydrolyzed (E1203), titanium dioxide (E171), macrogol (L 4000), talc (E553b), FD&C Blue #2/Indigo carmine aluminum lake (E132), iron oxide yellow (E172) (tablet coating)

What Cinacalcet Pharmazac looks like and contents of the pack

Cinacalcet Pharmazac are green oval biconvex coated tablets (approximately 4.5 x 7 mm), debossed with C9CC on one side and 30 on the other side.

Cinacalcet Pharmazac are green oval biconvex coated tablets (approximately 5.5 x 9 mm), debossed with C9CC on one side and 60 on the other side.

Cinacalcet Pharmazac are green oval biconvex coated tablets (approximately 6.5 x 10.5 mm), debossed with C9CC on one side and 90 on the other side.

Cinacalcet is available in PVC/PE/PVDC/Al transparent blisters containing 30 mg, 60 mg or 90 mg film-coated tablets. Blisters are packed in a box containing either 14, 28 or 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

PHARMAZAC S.A.
31 Naousis Str.
104 47 Athens, Greece

Manufacturer(s)

Synthon Hispania, S.L.
C/ Castelló no1, Pol. Les Salinas, Sant Boi de Llobregat
08830 Barcelona
Spain

Synthon, s.r.o.
Brněnská 32/čp. 597, Blansko, 678 01
Czech Republic

This medicinal product is authorised in the Member States of the EEA under the following names

Cyprus	Cinacalcet/Pharmazac 30 mg film-coated tablets Cinacalcet/Pharmazac 60 mg film-coated tablets Cinacalcet/Pharmazac 90 mg film-coated tablets
Greece	Cinacalcet/Pharmazac 30 mg, επικαλυμμένα με λεπτό υμένιο δισκία Cinacalcet/Pharmazac 60 mg, επικαλυμμένα με λεπτό υμένιο δισκία Cinacalcet/Pharmazac 90 mg, επικαλυμμένα με λεπτό υμένιο δισκία
Netherlands	Cinacalcet Pharmazac 30 mg, filmomhulde tabletten Cinacalcet Pharmazac 60 mg, filmomhulde tabletten Cinacalcet Pharmazac 90 mg, filmomhulde tabletten
Romania	Cinacalcet Pharmazac 30 mg, comprimate filmate Cinacalcet Pharmazac 60 mg, comprimate filmate Cinacalcet Pharmazac 90 mg, comprimate filmate

Deze bijsluiter is voor het laatst goedgekeurd in februari 2021.