

Package leaflet: Information for the patient

Cinacalcet Rafarm 30 mg filmomhulde tabletten

Cinacalcet Rafarm 60 mg filmomhulde tabletten

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

1. What <cinacalcet> is and what it is used for

<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).

<cinacalcet> 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 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.

<cinacalcet> 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>

Do not take <cinacalcet>:

- 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>.

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 and children 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 heart beat, 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 4.

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.

For children who require doses lower than 30 mg, or who are unable to swallow tablets, other dosage-strengths/pharmaceutical forms of cinacalcet are available.

Other medicines and <cinacalcet>

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 Mimpara together with etelcalcetide.

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.

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> 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> contains 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.

3. How to take <cinacalcet>

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.

<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.

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> is 30 mg (one tablet) once per day.

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

For children who require doses lower than 30 mg, or who are unable to swallow tablets, other dosage-strengths/pharmaceutical forms of cinacalcet are available.

If you are being treated for parathyroid cancer or primary hyperparathyroidism

The usual starting dose for <cinacalcet> is 30 mg (one tablet) twice per day.

If you take more <cinacalcet> than you should

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.

If you forget to take <cinacalcet>

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.

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> 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <cinacalcet>

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 medicinal product 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> contains

- The active substance is cinacalcet. Each film-coated tablet contains 30 mg, 60 mg or 90 mg of cinacalcet (as hydrochloride).
- The other ingredients are:
 - Pre-gelatinised starch (maize)
 - Microcrystalline cellulose (E480)
 - Crospovidone (E1202)
 - Magnesium stearate (E470b)
 - Colloidal anhydrous silica (E551)
- The tablets are coated with:
 - Sheffcoat Green L TN (contains Hydroxypropylmethyl Cellulose E464, Titanium Dioxide E171, Lactose Monohydrat, Triacetin/Glycerol Triacetate E1518, Yellow Iron Oxide E172, FD&C Blue#2/Indigotine Aluminum Lake (12-14%) E132).
 - Opadry clear (contains HPMC/Hypromellose, Macrogol/PEG E1521)

What <cinacalcet> looks like and contents of the pack

<cinacalcet> is a light green film-coated tablet. They are oval-shaped and have “30” marked on one side. (Width: 4.4 to 4.7 mm; Length: 6.9 to 7.2 mm)

<cinacalcet> is a light green film-coated tablet. They are oval-shaped and have “60” marked on one side. (Width: 5.5 to 5.7 mm; Length: 8.7 to 8.9 mm)

<cinacalcet> is a light green film-coated tablet. They are oval-shaped and have “90” marked on one side. (Width: 6.5 to 6.7 mm; Length: 9.9 to 10.2 mm)

<cinacalcet> is available in blisters 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 marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant:

Houder van de vergunning:

Rafarm S.A.

12 Korinthou str., N. Psihiko

154 51 Athene

Griekenland

Fabrikant:

Pharmadox Healthcare Ltd.

Address: KW20A Kordin Industrial Park

Paola PLA3000, Malta

RAFARM S.A.

Thesi Pousi-Xatzi Agiou Louka

Paiania Attiki, Post Code 19002, PO Box 37, Greece

In het register ingeschreven onder:

Cinacalcet Rafarm 30 mg filmomhulde tabletten RVG 121862

Cinacalcet Rafarm 60 mg filmomhulde tabletten RVG 121863

Cinacalcet Rafarm 90 mg filmomhulde tabletten RVG 121864

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Cyprus	CINACALCET/RAFARM 30 mg επικαλυμμένα με λεπτό υμένιο δισκία CINACALCET/RAFARM 60 mg επικαλυμμένα με λεπτό υμένιο δισκία CINACALCET/RAFARM 90 mg επικαλυμμένα με λεπτό υμένιο δισκία
Griekenland	CINACALCET/RAFARM 30 mg επικαλυμμένα με λεπτό υμένιο δισκία CINACALCET/RAFARM 60 mg επικαλυμμένα με λεπτό υμένιο δισκία CINACALCET/RAFARM 90 mg επικαλυμμένα με λεπτό υμένιο δισκία
Nederland	Cinacalcet Rafarm 30 mg filmomhulde tabletten Cinacalcet Rafarm 60 mg filmomhulde tabletten Cinacalcet Rafarm 90 mg filmomhulde tabletten

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: