

Package leaflet: Information for the patient

Cinacalcet Accord 30 mg film-coated tablets
Cinacalcet Accord 60 mg film-coated tablets
Cinacalcet Accord 90 mg film-coated tablets

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

1. What Cinacalcet Accord is and what it is used for

Cinacalcet Accord works by controlling the levels of parathyroid hormone (PTH), calcium and phosphorus 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 Accord 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.

Cinacalcet Accord 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 Accord

Do not take Cinacalcet Accord

- 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 Accord

Before you start taking Cinacalcet Accord, 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 Accord 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 Accord.

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 4.

During treatment with Cinacalcet Accord, 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 Accord.

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with Cinacalcet Accord and during treatment with Cinacalcet Accord. 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 Accord as advised by your doctor.

Other medicines and Cinacalcet Accord

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 Accord together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

Medicines such as these can affect how Cinacalcet Accord 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 Accord may affect how medicines such as the following work:

- medicines used to treat **depression** (amitriptyline, desipramine, nortriptyline and clomipramine);
- medicines 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 Accord with food and drink

Cinacalcet Accord 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 Accord

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 Accord 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 Accord

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how much cinacalcet you must take.

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

Cinacalcet is also available as granules for paediatric use. Children who require doses lower than 30 mg, or who are unable to swallow tablets should receive Cinacalcet granules .

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 Accord in adults is 30 mg (one tablet) once per day.

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

If you take more Cinacalcet Accord than you should

If you take more Cinacalcet Accord 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 Accord

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

If you have forgotten a dose of Cinacalcet Accord, 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 (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance Earlsfort Terrace,
IRL - Dublin 2;

Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie

5. How to store Cinacalcet Accord

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 Accord contains

- The active substance is cinacalcet. Each film-coated tablet contains 30mg, 60mg or 90mg of cinacalcet (as hydrochloride).
- The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinized starch, crospovidone, magnesium stearate and talc.
- The tablet coating contains hypromellose, titanium dioxide (E171), lactose monohydrate, triacetin, yellow iron oxide (E172) and indigo carmine lake (E132).

What Cinacalcet Accord looks like and contents of the pack

Cinacalcet Accord is a light green film-coated tablet. They are oval-shaped and have 'C' marked on one side and '30', '60' or '90' on the other side.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd.
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

S.C. Polisano Pharmaceuticals S.A., Alba Iulia Road 156, 550052 Sibiu, Sibiu County, Romania

Meditrial Internationals Ltd.,
Iztok Distr., 3 Charles Darwin Str.,
Sofia 1113,
Bulgaria

The medicinal product is authorized in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Austria	Cinacalcet Accord 30/60/90 mg filmtabletten
Czech Republic	Cinacalcet Accord 30/60/90 mg potahovaná tableta
Germany	Cinacalcet Accord 30/60/90 mg filmtabletten
Denmark	Cinacalcet Accord 30/60/90 mg filmovertrukne tabletter
France	Cinacalcet Accord 30/60/90 mg comprimé pelliculé
Ireland	Cinacalcet Accord 30/60/90 mg film-coated tablets
Italy	Cinacalcet Accord 30/60/90 mg compressa rivestita con film
Netherlands	Cinacalcet Accord 30/60/90 mg filmomhulde tabletten
Portugal	Cinacalcet Accord 30/60/90 mg comprimidos revestidos por película
Romania	Cinacalcet Accord 30/60/90 mg comprimate filmate
Sweden	Cinacalcet Accord 30/60/90 mg filmdragerad tablet
United Kingdom	Cinacalcet Accord 30/60/90 mg film-coated tablets
Finland	Cinacalcet Accord 30/60/90 mg kalvopäällysteiset tabletit
Bulgaria	Cinacalcet Accord 30/60/90 mg филмирани таблетки
Cyprus	Cinacalcet Accord 30/60/90 mg δισκία επικαλυμμένα με λεπτό υμένιο
Estonia	Cinacalcet Accord 30/60/90 mg õhukese polümeerikattega tabletid
Croatia	Sinacalcet Accord filmom obložene tablete
Iceland	Cinacalcet Accord filmuhúðaðar töflur
Lithuania	Cinacalcet Accord plėvele dengtos tabletės
Latvia	Cinacalcet Accord apvalkotās tabletes
Malta	Cinacalcet Accord 30/60/90 mg film-coated tablets
Norway	Cinacalcet Accord 30/60/90 mg filmdrasjerte tabletter
Poland	Cinacalcet Accord 30/60/90 mg tabletki powlekane
Slovak Republic	Cinacalcet Accord 30/60/90 mg filmom obalené tablety

This leaflet was last revised in 04/2020.