

Module 1.3	Product Information	Version: 2017-04-19
Module 1.3.1	Package Leaflet	Replaces : 2017-03-22

Package leaflet: Information for the patient

Cinacalcet Apotex 30 mg, film-coated tablets
Cinacalcet Apotex 60 mg, film-coated tablets
Cinacalcet Apotex 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 Apotex is and what it is used for
2. What you need to know before you take Cinacalcet Apotex
3. How to take Cinacalcet Apotex
4. Possible side effects
5. How to store Cinacalcet Apotex
6. Contents of the pack and other information

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

Cinacalcet Apotex 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 Apotex is used:

- 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.

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.

Module 1.3	Product Information	Version: 2017-04-19
Module 1.3.1	Package Leaflet	Replaces : 2017-03-22

2. What you need to know before you take Cinacalcet Apotex

Do not take Cinacalcet Apotex

- if you are allergic to Cinacalcet or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Cinacalcet Apotex

Before you start taking Cinacalcet Apotex, 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**.

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

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 Apotex.

For additional information see section 4.

During treatment with Cinacalcet Apotex, tell your doctor:

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

Children and adolescents

Children under the age of 18 must not take Cinacalcet Apotex.

Other medicines and Cinacalcet Apotex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking the following medicines.

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

Cinacalcet Apotex should be taken with or shortly after food.

Module 1.3	Product Information	Version: 2017-04-19
Module 1.3.1	Package Leaflet	Replaces : 2017-03-22

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

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

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Dizziness and seizures have been reported by patients taking Cinacalcet Apotex. If you experience these, your ability to drive or operate machinery may be affected.

3. How to take Cinacalcet Apotex

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 Apotex you must take.

Cinacalcet Apotex 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 Apotex 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 Apotex is 30 mg (one tablet) twice per day.

If you take more Cinacalcet Apotex than you should

If you take more Cinacalcet Apotex 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 Apotex

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

If you have forgotten a dose of Cinacalcet Apotex, 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.

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

Module 1.3	Product Information	Version: 2017-04-19
Module 1.3.1	Package Leaflet	Replaces : 2017-03-22

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

Children and adolescents

The use of Cinacalcet Apotex in children and adolescents has not been established. A fatal outcome was reported in an adolescent clinical trial patient with very low calcium levels in the blood (hypocalcaemia).

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 HPRAs Pharmacovigilance; Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971; Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

Module 1.3	Product Information	Version: 2017-04-19
Module 1.3.1	Package Leaflet	Replaces : 2017-03-22

5. How to store Cinacalcet Apotex

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 temperature storage conditions. Store in the original package in order to protect from light.

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 Apotex contains

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

The other ingredients are:

- Mannitol
- Cellulose, microcrystalline
- Sodium Starch Glycolate Type B
- Croscarmellose Sodium
- Silica, colloidal anhydrous
- Magnesium stearate

The tablets are coated with:

- Poly(vinyl alcohol)
- Macrogol 8000
- Talc
- Titanium Dioxide (E 171)
- Iron oxide yellow
- Brilliant blue FCF (E 133), lake
- Iron oxide black (E 172)

What Cinacalcet Apotex looks like and contents of the pack

- Light green colored, oval shaped (9.525 x 5.95 mm), biconvex film-coated tablets, engraved “APO” on one side and “C30” on the other side
- Light green colored, oval shaped (11.90 x 7.50 mm), biconvex film-coated tablets, engraved “APO” on one side and “C60” on the other side
- Light green colored, oval shaped (13.493 x 8.35 mm), biconvex film-coated tablets, engraved “APO” on one side and “C90” on the other side

Cinacalcet Apotex are available in blister packs of 28 or 84 film-coated tablets.

Module 1.3	Product Information	Version: 2017-04-19
Module 1.3.1	Package Leaflet	Replaces : 2017-03-22

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

Apotex Europe B.V.
Darwinweg 20
2333 CR Leiden
The Netherlands

Apotex Nederland BV
Archimedesweg 2, 2333 CN Leiden, The Netherlands

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

Hungary: Cinacalcet Apotex 30 mg, 60 mg and 90 mg, film-coated tablets
Ireland: Cinacalcet Apotex 30 mg, 60 mg and 90 mg, film-coated tablets
The Netherlands: Cinacalcet Apotex 30 mg, 60 mg and 90 mg, filmomhulde tabletten
Spain: Cinacalcet Apotex 30 mg, 60 mg and 90 mg, comprimidos recubiertos con película EFG
Poland: Cinacalcet Apotex

This leaflet was last revised in 04/2017