

Package leaflet: Information for the patient

Cinacalcet Rowex 30 mg film-coated tablets

Cinacalcet Rowex 60 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 Rowex is and what it is used for
2. What you need to know before you take Cinacalcet Rowex
3. How to take Cinacalcet Rowex
4. Possible side effects
5. How to store Cinacalcet Rowex
6. Contents of the pack and other information

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

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

Cinacalcet Rowex 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 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.

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

Do not take Cinacalcet Rowex if you are allergic to cinacalcet or any of the other ingredients of this medicine (listed in section 6).

Do not take Cinacalcet Rowex 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 Rowex.

Before you start taking Cinacalcet Rowex, 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 Rowex 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 Rowex.

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 Rowex.

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 Rowex.

For additional information see section 4.

During treatment with Cinacalcet Rowex, tell your doctor:

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

Children and adolescents

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

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

Other medicines and Cinacalcet Rowex

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 Rowex together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

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

Cinacalcet Rowex 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 Rowex 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 Rowex.

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 Rowex contains lactose

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

3. How to take Cinacalcet Rowex

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 Rowex you must take.

Cinacalcet Rowex must be taken orally, with or shortly after food. The tablets must be taken whole in order to be sure you will receive the correct dose and are not to be chewed, crushed or divided.

Cinacalcet is also available as granules in capsules for opening. 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 Rowex in adults is 30 mg (one tablet) once per day.

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

If you take more Cinacalcet Rowex than you should

If you take more Cinacalcet Rowex 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 Rowex

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

If you have forgotten a dose of Cinacalcet Rowex, 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 heartbeat 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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cinacalcet Rowex

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 Rowex contains

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

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate

The tablets are coated with:

Hypromellose, lactose monohydrate, triacetin (E 1518), titanium dioxide (E 171), yellow iron oxide (E 172), indigo carmine aluminium lake (E 132)

What Cinacalcet Rowex looks like and contents of the pack

30 mg: Light green, oval, biconvex, film-coated tablets having 'L83' debossed on one side and plain on other side (Approximate size 9.8 x 6.2 mm).

60 mg: Light green, oval, biconvex, film-coated tablets having 'L84' debossed on one side and plain on other side (Approximate size 12.4 x 7.8 mm).

Cinacalcet Rowex is available in blister packs.

Pack sizes: 28, 28x1, 30, 30x1, 84, 84x1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Sachsen-Anhalt, Germany.

Synoptis Industrial Sp. Z.o.o., ul. Szosa Bydgoska 58, 87-100 Torun, Poland.

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

Belgium	Cinacalcet Sandoz 30 mg filmomhulde tabletten Cinacalcet Sandoz 60 mg filmomhulde tabletten
Bulgaria	Цинакалцет Сандоз 30 mg филмирани таблетки
Czech Republic	Cinacalcet Sandoz
Denmark	Cinacalcet Sandoz
France	CINACALCET SANDOZ 30mg comprimé pelliculé CINACALCET SANDOZ 60mg comprimé pelliculé
Germany	Cinacalcet HEXAL 30 mg Filmtabletten Cinacalcet HEXAL 60 mg Filmtabletten
Greece	CINACALCET/SANDOZ, F.C.TAB 30MG/TAB, CINACALCET/SANDOZ, F.C.TAB 60MG/TAB

Ireland	Cinacalcet Rowex 30 mg film-coated tablets
	Cinacalcet Rowex 60 mg film-coated tablets
Italy	Cinacalcet Sandoz GmbH
The Netherlands	Cinacalcet Sandoz 30 mg, filmomhulde tabletten
	Cinacalcet Sandoz 60 mg, filmomhulde tabletten
Poland	Cinacalcet Sandoz
Spain	Cinacalcet Sandoz Farmacéutica 30 mg comprimidos recubiertos con película EFG
	Cinacalcet Sandoz Farmacéutica 60 mg comprimidos recubiertos con película EFG
Sweden	Cinacalcet Sandoz 30 mg filmdragerade tabletter
	Cinacalcet Sandoz 60 mg filmdragerade tabletter
United Kingdom	Cinacalcet 30mg film-coated Tablets
	Cinacalcet 60mg film-coated Tablets

This leaflet was last revised in 03/2022.