Package leaflet: Information for the user

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

1. What Cinacalcet Clonmel is and what it is used for
Cinacalcet Clonmel 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).

This medicine 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 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 Clonmel
DO NOT take Cinacalcet Clonmel:
- 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 Clonmel.

Before you start taking this medicine, 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 Clonmel 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 this medicine.

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 this medicine.

For additional information see section 4.

During treatment with this medicine, tell your doctor:
- if you start or stop smoking, as this may affect the way Cinacalcet Clonmel works

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

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.

Note:
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 Clonmel
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 Clonmel together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

Medicines such as these can affect how Cinacalcet Clonmel 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 Clonmel 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 Clonmel with food and drink
This medicine 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 Clonmel has not been tested in pregnant women. In case of pregnancy, your doctor may decide to modify your treatment, as this medicine might harm the unborn baby.

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

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 Clonmel contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Cinacalcet Clonmel
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 Clonmel you must take.

Dosage
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 recommended starting dose for this medicine in adults is 30 mg once per day.

The recommended 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.

Note:
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 recommended starting dose for this medicine in adults is 30 mg twice per day.

Method of administration
This medicine must be taken orally, with or shortly after food. The tablets must be taken whole and are not to be chewed, crushed or divided.
The score line is not intended for breaking the tablet.

If you take more Cinacalcet Clonmel than you should
If you take more of this medicine 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 Clonmel
Do not take a double dose to make up for a forgotten dose.

If you have forgotten a dose of this medicine, 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)
- 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, upper abdominal pain
- 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:
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 Clonmel
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 humidity.

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 Clonmel contains

The active substance of Cinacalcet Clonmel is cinacalcet (as hydrochloride).

Each film-coated tablet contains 30 mg cinacalcet (as hydrochloride).
Each film-coated tablet contains 60 mg cinacalcet (as hydrochloride).
Each film-coated tablet contains 90 mg cinacalcet (as hydrochloride).

The other ingredients are

Tablet core:
Microcrystalline cellulose, maltodextrin, silica (colloidal anhydrous), crospovidone, sodium starch glycolate, magnesium stearate

Tablet coat:
Hypromellose, titanium dioxide E171, triacetin, iron oxide yellow E172, indigotine aluminium lake E132

What Cinacalcet Clonmel looks like and contents of the pack

Cinacalcet Clonmel 30 mg film-coated tablets are green, oval, biconvex film-coated tablets.
They are available in blister packs of PVC/PCTFE/PVC//Al.
Cinacalcet Clonmel 60 mg film-coated tablets are green, oval, biconvex film-coated tablets with an embossed line on one side.
They are available in blister packs of PVC/PCTFE/PVC//Al.
Cinacalcet Clonmel 90 mg film-coated tablets are green, oval, biconvex film-coated tablets.
They are available in blister packs of PVC/PCTFE/PVC//Al.

Cinacalcet Clonmel film-coated tablets are available in packs of:
For 30 mg: 28, 30, 50 and 84 film-coated tablets or 28x1, 30x1, 50x1, 84x1 film-coated tablet (unit-dose)
For 60 mg: 28, 30 and 84 film-coated tablets or 28x1, 30x1, 84x1 film-coated tablet (unit-dose)
For 90 mg: 28, 30 and 84 film-coated tablets or 28x1, 30x1, 84x1 film-coated tablet (unit-dose)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
STADA Arzneimittel AG, Stadastraße 2-18, D-61118 Bad Vilbel, Germany
STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria
Centrafarm Services B.V., Van de Reijtstraat 31-E, 4814 NE Breda, Netherlands
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
Thornton & Ross Ltd, Linthwaite, Huddersfield, West Yorkshire HD7 5QH, UK

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

Austria	Cinacalcet STADA 30 mg Filmtabletten
	Cinacalcet STADA 60 mg Filmtabletten
	Cinacalcet STADA 90 mg Filmtabletten

Czech Republic	Cinacalcet STADA 30 mg potahované tablety Cinacalcet STADA 60 mg potahované tablety Cinacalcet STADA 90 mg potahované tablety
Germany	Cinacalcet AL 30 mg Filmtabletten Cinacalcet AL 60 mg Filmtabletten Cinacalcet AL 90 mg Filmtabletten
Denmark	Cinacalcet STADA 30 mg Cinacalcet STADA 60 mg Cinacalcet STADA 90 mg
Spain	Cinacalcet STADA 30 mg comprimidos recubiertos con película EFG Cinacalcet STADA 60 mg comprimidos recubiertos con película EFG Cinacalcet STADA 90 mg comprimidos recubiertos con película EFG
Finland	Cinacalcet STADA 30 mg kalvopäällysteiset tabletit Cinacalcet STADA 60 mg kalvopäällysteiset tabletit Cinacalcet STADA 90 mg kalvopäällysteiset tabletit
France	Cinacalcet EG 30 mg, comprimé pelliculé Cinacalcet EG 60 mg, comprimé pelliculé Cinacalcet EG 90 mg, comprimé pelliculé
Ireland	Cinacalcet Clonmel 30 mg film-coated tablets Cinacalcet Clonmel 60 mg film-coated tablets Cinacalcet Clonmel 90 mg film-coated tablets
Iceland	Cinacalcet STADA
Italy	Cinacalcet EG
Netherlands	Cinacalcet CF 30 mg, filmomhulde tabletten Cinacalcet CF 60 mg, filmomhulde tabletten Cinacalcet CF 90 mg, filmomhulde tabletten
Norway	Cinacalcet STADA
Sweden	Cinacalcet STADA 30 mg filmdragerade tabletter Cinacalcet STADA 60 mg filmdragerade tabletter Cinacalcet STADA 90 mg filmdragerade tabletter
United Kingdom	Cinacalcet STADA 30 mg film-coated tablet Cinacalcet STADA 60 mg film-coated tablet Cinacalcet STADA 90 mg film-coated tablet

This leaflet was last revised in November 2021.