

Package leaflet: Information for the patient

<PRODUCT NAME> 30 mg film-coated tablets

<PRODUCT NAME> 60 mg film-coated tablets

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

1. What <PRODUCT NAME> is and what it is used for

<PRODUCT NAME> 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).

<PRODUCT NAME> 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.

<PRODUCT NAME> 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 <PRODUCT NAME>

Do not take <PRODUCT NAME>

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

Do not take <PRODUCT NAME> 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 <PRODUCT NAME>

Before you start taking <PRODUCT NAME>, 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**.

<PRODUCT NAME> reduces calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in adults and children treated with <PRODUCT NAME>.

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 <PRODUCT NAME>.

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 <PRODUCT NAME>.

For additional information see section 4.

During treatment with <PRODUCT NAME>, tell your doctor:

- if you start or stop smoking, as this may affect the way <PRODUCT NAME> works.

Children and adolescents

Children under the age of 18 with parathyroid cancer or primary hyperparathyroidism must not take <PRODUCT NAME>.

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

Other medicines and <PRODUCT NAME>

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines particularly etelcalcetide or any other medicines that lower the level of calcium in your blood.

You should not receive <PRODUCT NAME> together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

Medicines such as these can affect how <PRODUCT NAME> 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).

<PRODUCT NAME> 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).

<PRODUCT NAME> with food and drink

<PRODUCT NAME> 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.

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

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

Driving and using machines

Dizziness and seizures have been reported by patients taking <PRODUCT NAME>. If you experience these side effects, do not drive or operate machines.

3. How to take <PRODUCT NAME>

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 <PRODUCT NAME> you must take.

<PRODUCT NAME> must be taken orally, with or shortly after food. The tablets must be taken whole and are not to be chewed, crushed or divided.

For children who require doses lower than 30 mg, or who are unable to swallow tablets other dosage forms are available.

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 <PRODUCT NAME> in adults is 30 mg (one tablet) once per day.

The usual starting dose of <PRODUCT NAME> 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 <PRODUCT NAME> in adults is 30 mg (one tablet) twice per day.

If you take more <PRODUCT NAME> than you should

If you take more <PRODUCT NAME> 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 <PRODUCT NAME>

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

If you have forgotten a dose of <PRODUCT NAME>, 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 the 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 <PRODUCT NAME> 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 <PRODUCT NAME>

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.

Do not use this medicine after the expiry date which is stated on the carton and bottle. 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 <PRODUCT NAME> 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 maize starch
 - microcrystalline cellulose
 - crospovidone
 - magnesium stearate
 - colloidal anhydrous silica
- The tablets are coated with:
Opadry green [containing polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, yellow iron oxide (E172), indigo carmine aluminium lake (E132)]

What <PRODUCT NAME> looks like and contents of the pack

<PRODUCT NAME> is a light green to green film-coated tablet. They are oval-shaped and have “C30”, “C60” or “C90” marked on one side and plain on the other side.

<PRODUCT NAME> is available in blisters of 30 mg, 60 mg or 90 mg film-coated tablets. Each blister pack contains either 14, 28, 30, 84 or 98 tablets in a carton.

<PRODUCT NAME> is also available in unit dose blisters of 30 mg, 60 mg or 90 mg film-coated tablets. Each unit dose blister pack contains either 14, 28, 30, 84 or 98 tablets in a carton.

<PRODUCT NAME> is available in bottles of 30 mg, 60 mg or 90 mg film-coated tablets, inside a carton. Each bottle holds 30 tablets. Bottles are available with or without a silica gel desiccant. Do not eat the desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Austria:	Cinacalcet ratiopharm 30 mg Filmtabletten, Cinacalcet ratiopharm 60 mg Filmtabletten, Cinacalcet ratiopharm 90 mg Filmtabletten
Bulgaria:	Cinacalcet Teva 30 mg film-coated tablets
Denmark:	Cinacalcet Teva
Estonia:	Cinacalcet Teva
France:	CINACALCET TEVA 30 mg, comprimé pelliculé, CINACALCET TEVA 60 mg, comprimé pelliculé, CINACALCET TEVA 90 mg, comprimé pelliculé
Finland:	Cinacalcet ratiopharm 30 mg tabletti, kalvopäällysteinen, Cinacalcet ratiopharm 60 mg tabletti, kalvopäällysteinen, Cinacalcet ratiopharm 90 mg tabletti, kalvopäällysteinen
Germany:	Cinacalcet-ratiopharm 30 mg Filmtabletten, Cinacalcet-ratiopharm 60 mg Filmtabletten, Cinacalcet-ratiopharm 90 mg Filmtabletten
Greece:	Cinacalcet/Teva 30 mg Επικαλυμμένα με λεπτό υμένιο δισκία, Cinacalcet/Teva 60 mg Επικαλυμμένα με λεπτό υμένιο δισκία, Cinacalcet/Teva 90 mg Επικαλυμμένα με λεπτό υμένιο δισκία
Ireland:	Cinacalcet Teva 30 mg, 60 mg and 90 mg Film-coated Tablets
Italy:	Cinacalcet Teva
Latvia:	Cinacalcet Teva 30 mg apvalkotās tabletes, Cinacalcet Teva 60 mg apvalkotās tabletes
Lithuania:	Cinacalcet Teva 30 mg plėvele dengtos tabletės, Cinacalcet Teva 60 mg plėvele dengtos tabletės, Cinacalcet Teva 90 mg plėvele dengtos tabletės
Netherlands:	Cinacalcet HCl Teva 30 mg, 60 mg, 90 mg filmomhulde tabletten
Norway:	Cinacalcet Teva
Portugal:	Cinacalcet Teva
Slovakia:	Cinacalcet Teva 30 mg filmom obalené tablety, Cinacalcet Teva 60 mg filmom obalené tablety, Cinacalcet Teva 90 mg filmom obalené tablety
Spain:	Cinacalcet Teva 30 mg, 60 mg and 90 mg comprimidos recubiertos con película EFG
Sweden:	Cinacalcet Teva

This leaflet was last revised in {MM/YYYY}.

[To be completed nationally]

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Teva Pharmaceuticals Europe B.V

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APPROVALS

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Sunita Hadawale	Regulatory Affairs Approval	03-Apr-2020 09:10:54 AM