

PRODUCT

Cinacalcet Teva 30mg, 60mg, 90mg FC Tabs All TEI KS V2

Component

Dimensions

SAP No.

Leaflet

190x380mm

NA

COLOURS

Cutterguide  
Black  
PMS Green

FONTS

Univers  
Body Size 9pt

ARTWORK

FIRST DRAFT  
Artworker  
Date

AMENDS

Draft

Artworker

Date

APPROVAL

ARTWORKER  
Signed  
Date

PLANNER

Signed

Date

Supplier Instructions: Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please contact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendors Proof before final approval can be made.

Viewing Instructions:

To ensure this file views correctly, please set overprint preview to 'ALWAYS' in your Adobe Acrobat preferences.

Acrobat → Preferences → Page Display → Use Overprint Preview → Always

When overprint preview is set up correctly there should be no 'X' appearing in any box marked A-D. Please follow the instructions above if you see an 'X'.

JB V 10.10.ind

2329

CINACALCET TEVA 30 mg  
FILM-COATED TABLETS  
CINACALCET TEVA 60 mg  
FILM-COATED TABLETS  
CINACALCET TEVA 90 mg  
FILM-COATED TABLETS  
cinacalcet

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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

1 What Cinacalcet Teva is and what it is used for

Cinacalcet Teva 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 Teva 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 Teva 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 Teva

Do not take Cinacalcet Teva

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

Do not take Cinacalcet Teva 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 Teva

Before you start taking Cinacalcet Teva, 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 Teva 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 Teva.

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 Teva.

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 Teva.

For additional information see section 4.

During treatment with Cinacalcet Teva, tell your doctor:

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

Children and adolescents

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

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

Other medicines and Cinacalcet Teva

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 Cinacalcet Teva together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

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

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

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

Driving and using machines

Dizziness and seizures have been reported by patients taking Cinacalcet Teva. If you experience these side effects, do not drive or operate machines.

3 How to take Cinacalcet Teva

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 Teva you must take.

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

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

If you take more Cinacalcet Teva than you should

If you take more Cinacalcet Teva 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 Teva

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

If you have forgotten a dose of Cinacalcet Teva, 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 Cinacalcet Teva 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](http://www.hpra.ie).

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

#### 5 How to store Cinacalcet Teva

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 Cinacalcet Teva 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 Cinacalcet Teva looks like and contents of the pack**  
Cinacalcet Teva 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.

Cinacalcet Teva 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.

Cinacalcet Teva 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.

Cinacalcet Teva 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**

**Marketing Authorisation Holder**

Teva B.V.  
Swensweg 5  
2031GA Haarlem  
The Netherlands

**Manufacturer**

Teva Operations Poland Sp. z o.o  
ul. Mogilska 80. , Krakow  
31-546  
Poland

Merckle GmbH  
Ludwig-Merckle-Straße 3, Blaubeuren  
89143  
Germany

Teva Pharma B.V.  
Swensweg 5, Haarlem  
2031 GA  
The Netherlands

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)  
Prilaz baruna Filipovica 25, Zagreb  
10000  
Croatia

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

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

**This leaflet was last revised in June 2020.**