PACKAGE LEAFLET

Package leaflet: Information for the patient

Cinacalcet Tillomed 30mg, 60mg and 90mg 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 or 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 or 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 is and what it is used for
2. What you need to know before you take Cinacalcet
3. How to take Cinacalcet
4. Possible side effects
5. How to store Cinacalcet
6. Contents of the pack and other information

1. What Cinacalcet is and what it is used for

Cinacalcet 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 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 is not to be used in children aged 3 years to less than 18 years of age:

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.

The name of your medicine is Cinacalcet Tillomed Film-coated Tablets, but will be referred to as Cinacalcet throughout this leaflet.

2. What you need to know before you take Cinacalcet

Do not take Cinacalcet

• if you are allergic (hypersensitive) 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 or pharmacist before taking Cinacalcet

Before you start taking Cinacalcet, 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 reduces calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in adults 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 Cinacalcet.

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.

For additional information see section 4.

During treatment with Cinacalcet, tell your doctor:

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

Children and adolescents

Cinacalcet must not be given to children under the age of 18 with parathyroid cancer or primary hyperparathyroidism.

Other medicines and Cinacalcet

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 together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

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

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 Tillomed contains lactose

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

3. How to take Cinacalcet

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 you must take.

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

Your doctor will take regular blood samples during treatment to monitor your progress and will adjust your dose if necessary.

<u>If you are being treated for secondary hyperparathyroidism</u>
The usual starting dose for Cinacalcet in adults is 30 mg (one tablet) once per day.

<u>If you are being treated for parathyroid cancer or primary hyperparathyroidism</u>

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

If you take more Cinacalcet than you should

If you take more Cinacalcet 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

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

If you have forgotten a dose of Cinacalcet, 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, 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cinacalcet

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 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 Tillomed 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:
  - **Tablet core**: microcrystalline cellulose, low substituted hydroxyl propyl, cellulose, lactose monohydrate, silica colloidal anhydrous, magnesium stearate
  - **Tablet coating**:
    HPMC 2910/Hypromellose (E464)
    Lactose Monohydrate
    Titanium dioxide (E171)
    Triacetin
    FD&C Blue #2/Indigo Carmine AL 3%- 5% (E132)
    Iron Oxide Yellow (E172)

What Cinacalcet Tillomed looks like and contents of the pack

The 30 mg tablets are light green oval shaped biconvex film coated tablets debossed with "HP" on one side and "363" on other side
The 60 mg tablets are light green oval shaped biconvex film coated tablets debossed with "HP" on one side and "364" on other side.
The 90 mg tablets are light green oval shaped biconvex film coated tablets debossed with "HP" on one side and "365" on other side
Cinacalcet Tillomed are available in unit dose blister packs of 28 and 84 tablets

Not all pack sizes may be marketed

High Density Polyethylene (HDPE) bottle pack with 30 tablets

Marketing Authorisation Holder & Manufacturer

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