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**Package leaflet: Information for the patient**

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


## 1. What Cinacalcet Accordpharma is and what it is used for

Cinacalcet Accordpharma contains the active ingredient cinacalcet, which 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 Accordpharma 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 Accordpharma 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 Accordpharma

**Do not take Cinacalcet Accordpharma:**
- 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 Accordpharma.

Before you start taking Cinacalcet Accordpharma, 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 Accordpharma 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 Accordpharma.

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 Accordpharma.

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 Accordpharma.

For additional information see section 4.

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

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

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with Cinacalcet Accordpharma and during treatment with Cinacalcet Accordpharma. You should inform your doctor if you experience any of the signs of low calcium levels as described above.

Cinacalcet Accordpharma is only available as film-coated tablet. Thus, it is not possible to administer Cinacalcet Accordpharma to paediatric patients that require less than a full 30 mg dose. If an alternate dose is required, other cinacalcet medicines offering such an option should be used.

It is important that you take your dose of Cinacalcet Accordpharma as advised by your doctor.

**Other medicines and Cinacalcet Accordpharma**
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 Accordpharma together with etelcalcetide.

Tell your doctor if you are taking the following medicines

Medicines such as these can affect how Cinacalcet Accordpharma 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 Accordpharma 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).

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

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

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

## 3. How to take Cinacalcet Accordpharma

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 Accordpharma you must take.

Cinacalcet Accordpharma 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.

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

The usual starting dose of Cinacalcet Accordpharma for children aged 3 years to less than 18 years of age is no more than 0.20 mg/kg of body weight daily.

Cinacalcet Accordpharma is only available as film-coated tablet. Thus, it is not possible to administer Cinacalcet Accordpharma to paediatric patients who require doses lower than 30 mg, or who are unable to swallow tablets. If an alternate dose or form of this medicine is required, other cinacalcet medicines offering such an option should be used; ask your doctor or pharmacist.

*If you are being treated for parathyroid cancer or primary hyperparathyroidism*
The usual starting dose for Cinacalcet Accordpharma in adults is 30 mg (one tablet) twice per day.

**If you take more Cinacalcet Accordpharma than you should**
If you took more Cinacalcet Accordpharma 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 Accordpharma**
Do not take a double dose to make up for a forgotten dose.
If you have forgotten a dose of Cinacalcet Accordpharma, 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 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 Accordpharma 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 or. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: 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 Accordpharma

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 Accordpharma 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:
  - Cellulose, microcrystalline
  - Crospovidone
  - Magnesium stearate
  - Cysteine hydrochloride
- The tablets are coated with:
  - Hypromellose (E464),
  - Titanium dioxide (E171),
  - Triacetin,
  - Indigo carmine aluminum lake (E132),
  - Iron oxide yellow (E172)

**What Cinacalcet Accordpharma looks like and contents of the pack**

<u>Cinacalcet Accordpharma 30 mg film-coated tablets (tablet)</u>

Light green colored, oval shaped (approximately 9.65 mm long and 6.00 mm wide), biconvex, film-coated tablets debossed with "HB1" on one side and plain on other side.

<u>Cinacalcet Accordpharma 60 mg film-coated tablets (tablet)</u>

Light green colored, oval shaped (approximately 12.20 mm long and 7.60 mm wide), biconvex, film-coated tablets debossed with "HB2" on one side and plain on other side.

<u>Cinacalcet Accordpharma 90 mg film-coated tablets (tablet)</u>

Light green colored, oval shaped (approximately 14.00 mm long and 8.70 mm wide), biconvex, film-coated tablets debossed with "HB3" on one side and plain on other side.

Cinacalcet Accordpharma is available in blisters of 30 mg, 60 mg or 90 mg film-coated tablets. Cinacalcet Accordpharma is provided in PVC/Alu blister or OPA/alu/PVC/desiccant PE/alu/PE blister packs containing 14, 28 or 84 tablets and unit dose blister containing 14 x 1, 28 x 1 or 84 x 1 tablet.
Cinacalcet Accordpharma is available in bottles of 30 mg, 60 mg or 90 mg film-coated tablets. Each bottle holds 30 film-coated tablets.
Not all pack sizes may be marketed.

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