



CINACALCET Devatis 30 mg, 60 mg & 90 mg Film Coated Tablets

Cinacalcet hydrochloride

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using CINACALCET Devatis Film Coated Tablets.

This leaflet answers some common questions about CINACALCET Devatis Film Coated Tablets. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CINACALCET Devatis Film Coated Tablets against the benefits he/she expects it will have for you.

If you have any concerns about taking CINACALCET Devatis Film Coated Tablets, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What CINACALCET Devatis Film Coated Tablets is used for

Cinacalcet is used to treat:

- a condition called secondary hyperparathyroidism (high-per-pear-a-THIGH-royd-izm) in people with kidney disease who require dialysis treatment.
- a condition called primary hyperparathyroidism when surgical removal of the parathyroid gland is not a treatment option.
- high blood calcium levels in people with cancer of the parathyroid gland

Secondary hyperparathyroidism

Kidney disease can cause a condition called secondary hyperparathyroidism, which can have a big impact on your health. Four small glands located behind the thyroid gland in your neck are called parathyroid glands. They make a hormone called parathyroid hormone (PTH). Normally, PTH makes sure you have just enough calcium and phosphorus in your blood to keep your bones, heart, muscles, nerves and blood vessels working well. When your kidneys are working, PTH keeps your calcium and phosphorus levels normal by moving the right amounts of calcium and phosphorus in and out of your bones.

When your kidneys aren't working properly, the calcium and phosphorus balance in your body is upset, and your parathyroid glands send out too much PTH to your body. This condition is called secondary hyperparathyroidism, and it can cause bone disease and also may be a risk factor for heart disease and abnormal calcium deposits in blood vessels and other parts of the body. Cinacalcet lowers PTH by telling your parathyroid glands to stop releasing too much PTH into your blood. It also lowers your calcium and phosphorus levels.

Primary hyperparathyroidism/Cancer of the parathyroid gland

An overactive parathyroid gland results in a condition called primary hyperparathyroidism, which can impact on your health. Four small glands located behind the thyroid gland in your neck are called parathyroid glands.

They make a hormone called parathyroid hormone (PTH). When your parathyroid glands are working normally, PTH keeps your calcium levels normal by moving the right amounts of calcium in and out of your bones.

Primary hyperparathyroidism is caused by an enlargement of one or more of the parathyroid glands occasionally due to cancer of the parathyroid gland. In primary hyperparathyroidism, your parathyroid glands send out too much PTH to your body and your blood level of calcium becomes high. Cinacalcet lowers PTH by telling your parathyroid glands to stop releasing too much PTH into your blood. It also lowers your blood calcium levels.

Your doctor may have prescribed CINACALCET Devatis Film Coated Tablets for another reason. Ask your doctor if you have any questions about why CINACALCET Devatis Film Coated Tablets has been prescribed for you.

Before you take CINACALCET Devatis Film Coated Tablets

When you must not take CINACALCET Devatis Film Coated Tablets

Do not take Cinacalcet if you are allergic to the active ingredient or any of the ingredients in Cinacalcet listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Talk to your doctor, nurse or pharmacist if you have any questions about this information.

Do not give Cinacalcet to a child. There is not enough information at present to recommend use of **Cinacalcet** in children.

Do not take Cinacalcet after the expiry date (Exp.) stamped on the pack. If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Cinacalcet if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.

If you are not sure whether you should start using CINACALCET Devatis Film Coated Tablets, talk to your doctor.

Before you start to take CINACALCET Devatis Film Coated Tablets

Tell your doctor:

1. If you have or have had any medical conditions, including

- **seizures** (sometimes called fits or convulsions, see ‘Side effects’ section)
- **heart failure** (or a heart condition, see ‘Side effects’ section)
- **intolerance to sugars** (sometimes called lactose intolerance, see ‘Ingredients’ section)

2. If you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking Cinacalcet if you are pregnant.

3. If you are breastfeeding or planning to breastfeed. It is not known whether Cinacalcet passes into breast milk.

If you have not told your doctor about any of the above, tell him/her before you take CINACALCET Devatis Film Coated Tablets.

Taking other medicines

Tell your doctor if you are taking ketoconazole, erythromycin, itraconazole, rifampicin, phenytoin, amitriptyline, flecainide, vinblastine, thioridazine or medicines known as tricyclic antidepressants. Some of these medicines can affect how Cinacalcet works, while others are affected by Cinacalcet.

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines you buy without a prescription from a pharmacy, supermarket or health food shop (for example St John's Wort).

How to take CINACALCET Devatis Film Coated Tablets

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

Follow all directions given to you by your doctor, nurse and pharmacist carefully. They may differ from the information in this leaflet.

If you do not understand the instructions below, ask your doctor, nurse or pharmacist for help.

How much Cinacalcet to take

If you are being treated for secondary hyperparathyroidism

The usual starting dose for Cinacalcet is 30 mg (one tablet) once per day. Your doctor will take regular blood samples to measure how you are responding to Cinacalcet and will adjust your dose as necessary in order to control your parathyroid hormone, calcium and phosphate levels.

Once your condition is under control, your doctor will continue to regularly check your blood and your dose may be adjusted further in order to maintain long-term control of your parathyroid hormone, calcium and phosphate levels.

If you are being treated for primary hyperparathyroidism/cancer of the parathyroid gland

The usual starting dose for Cinacalcet is 30 mg (one tablet) twice per day. Your doctor will take regular blood samples to measure how you are responding to Cinacalcet and will adjust your dose as necessary in order to control your calcium levels.

Once your condition is under control, your doctor will continue to regularly check your blood and your dose may be adjusted further in order to maintain long-term control of your calcium levels.

If you forget to take CINACALCET Devatis Film Coated Tablets

If you have forgotten a dose of Cinacalcet, you should take your next dose as normal.

If you take more Cinacalcet than you should (overdose)

If you take more Cinacalcet than you should you must contact your doctor, nurse or pharmacist immediately.

While you are taking CINACALCET Devatis Film Coated Tablets

Things you must do

Always follow your doctor's instructions carefully.

If you are about to start using a new medicine, tell your doctor, nurse and pharmacist that you are taking CINACALCET Devatis Film Coated Tablets.

If you become pregnant while you are taking Cinacalcet, tell your doctor.

Things you must not do

Do not take CINACALCET Devatis Film Coated Tablets to treat any other complaint unless your doctor says so.

Do not give CINACALCET Devatis Film Coated Tablets to anyone else, even if their symptoms seem similar to yours.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much CINACALCET Devatis Film Coated Tablets.

Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor as soon as possible if you have any problems while taking CINACALCET Devatis Film Coated Tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Cinacalcet may cause side effects. Some side effects may be serious and need medical attention. Other side effects are minor and are likely to be temporary.

Cinacalcet lowers your calcium level. If calcium levels become too low, you might get hypocalcemia. Signs of hypocalcemia include numbness or tingling around the mouth, muscle aches or cramps and seizures. If you have any of these symptoms, you should tell your doctor straight away. People with kidney disease not requiring dialysis are at increased risk of developing hypocalcemia.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

If any of the following happens, stop taking CINACALCET Devatis Film Coated Tablets and go straight to the hospital, as you may need urgent medical attention:

- Allergic reaction
- Skin rash over a large area of the body
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Shortness of breath
- Wheezing

- **Faintness, rapid pulse or sweating**

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- **Nausea and vomiting**
People taking Cinacalcet have a greater chance of developing nausea and /or vomiting. If nausea or vomiting is making it difficult to take your medicines or is of any concern to you, you should tell your doctor.
- **Seizure (also known as a fit or convulsion)**
The risk of having seizures is greater in people who have had seizures before. Lowering the calcium level too much may also increase the risk of having a seizure. If you have a seizure you should tell your doctor straight away.
- **Dizziness or light headedness, or worsening of a heart condition**
Cinacalcet may cause low blood pressure or affect the heart's function in people who have a heart condition (heart failure). If you know you have a heart condition, tell your doctor.
- **Rash**
Pinkish, itchy swellings on the skin, also called hives or nettle rash. Itchy rash.

Tell your doctor, nurse or pharmacist if you notice anything that worries you or that is making you feel unwell, even if it is not on this list.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After taking CINACALCET Devatis Film Coated Tablets

Storage

Cinacalcet does not require any special temperature storage conditions.

The expiry date (Exp.) for CINACALCET Devatis Film Coated Tablets is stamped on the outer box and the blister label. Do not take CINACALCET Devatis Film Coated Tablets after this date, the last day of the month shown.

As with all medicines, you should keep CINACALCET Devatis Film Coated Tablets out of the reach and sight of children.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

CINACALCET Devatis Film Coated Tablet is a light green film-coated tablet. They are oval-shaped and have "30", "60" or "90" marked on one side. Each tablet contains 30 mg, 60 mg or 90 mg of cinacalcet. They come in blister packs. Each pack contains 28 tablets.



Ingredients

Active ingredient:

The active ingredient in CINACALCET Devatis Film Coated Tablets is cinacalcet hydrochloride.

Other ingredients:

The other ingredients of CINACALCET Devatis Film Coated Tablets are cellulose microcrystalline, starch pregelatinized, crospovidone, silica colloidal anhydrous, magnesium stearate.

The tablets are coated with color (SheffCoatGreen L TN 1264G49), a clear film-coat (Opadry Clear (OY29020)).

If you have been told by your doctor that you have an intolerance to certain sugars (for example, lactose), tell your doctor before taking CINACALCET Devatis Film Coated Tablets.

Sponsor

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