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1.3.1 spc-label-pl - common-pl - 10,415 (DK/H/2470/001-002-003/IB/006)		20190314
CINACALCET HYDROCHLORIDE 30 MG 60 MG 90 MG FILM-COATED TABLET		722-2372.00 722-2373.00 722-2374.00

PACKAGE LEAFLET

Package leaflet: Information for the patient

{[Nationally completed name] 30 mg film-coated tablets}
{[Nationally completed name] 60 mg film-coated tablets}
{[Nationally completed 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 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 [nationally completed name] is and what it is used for
2. What you need to know before you take [nationally completed name]
3. How to take [nationally completed name]
4. Possible side effects
5. How to store [nationally completed name]
6. Contents of the pack and other information

1. What {nationally completed name} is and what it is used for

{Nationally completed 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).

{Nationally completed 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.

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- to reduce high levels of calcium in the blood (hypercalcaemia) in adult patients with primary hyperparathyroidism when removal of the gland is not possible.

{nationally completed 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 {nationally completed name}

Do not take {nationally completed name}:

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

Do not take {nationally completed 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 {nationally completed name}

Before you start taking {nationally completed 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**.

{nationally completed 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 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 {nationally completed 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 {nationally completed name}.

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For additional information see section 4.

During treatment with {nationally completed name}, tell your doctor:

- if you start or stop smoking, as this may affect the way {nationally completed name} works.

Children and adolescents

Children under the age of 18 with parathyroid cancer or primary hyperparathyroidism must not take {nationally completed name}

If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with {nationally completed name} and during treatment with {nationally completed 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 {nationally completed name} as advised by your doctor.

Other medicines and {nationally completed name}

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 {nationally completed name} together with etelcalcetide.

Tell your doctor if you are taking the following medicines:

Medicines such as these can affect how {nationally completed 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).

{Nationally completed 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).

{Nationally completed name} with food and drink

{Nationally completed 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.

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Cinacalcet has not been tested in pregnant women. In case of pregnancy, your doctor may decide to modify your treatment, as {nationally completed name} 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 {nationally completed name}.

Driving and using machines

Dizziness and seizures have been reported by patients taking {nationally completed name}. If you experience these side effects, do not drive or operate machines.

3. How to take {nationally completed 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 {nationally completed name} you must take.

{Nationally completed 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.

Cinacalcet is also available as granules in capsules for opening. Children who require doses lower than 30 mg, or who are unable to swallow tablets should receive Cinacalcet granules.

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 {nationally completed name} is 30 mg (one tablet) once per day.

The usual starting dose of {nationally completed 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 {nationally completed name} in adults is 30 mg (one tablet) twice per day.

If you take more {nationally completed name} than you should

If you take more {nationally completed 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 {nationally completed name}

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

If you have forgotten a dose of {nationally completed 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.

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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
- low calcium levels in the blood (hypocalcaemia)
- back pain.

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)

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- 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 {nationally completed 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 {Nationally completed 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.

This medicine 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 {Nationally completed name} contains

The active substance is cinacalcet.

{[Nationally completed name] 30 mg film-coated tablets}:
Each film-coated tablet contains 30 mg cinacalcet (as hydrochloride).

{[Nationally completed name] 60 mg film-coated tablets}:
Each film-coated tablet contains 60 mg cinacalcet (as hydrochloride).

{[Nationally completed name] 90 mg film-coated tablets}:
Each film-coated tablet contains 90 mg cinacalcet (as hydrochloride).

The other ingredients are:

Tablet core:

Partially pregelatinised maize starch, microcrystalline cellulose, povidone K29/32, crospovidone type A, crospovidone type B, magnesium stearate, colloidal anhydrous silica

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Tablet coating:

Polyvinyl alcohol-partially hydrolyzed, titanium dioxide, macrogol 4000, talc, Indigo carmine aluminum lake (E132), iron oxide yellow (E172)

What {Nationally completed name} looks like and contents of the pack

{[Nationally completed name] 30 mg film-coated tablets} are green oval biconvex film-coated tablets (dimension: 4.5 x 7 mm), debossed with 'C9CC' on one side and '30' on the other side.

{[Nationally completed name] 60 mg film-coated tablets} are green oval biconvex film-coated tablets (dimension: 5.5 x 9 mm), debossed with 'C9CC' on one side and '60' on the other side.

{[Nationally completed name] 90 mg film-coated tablets} are green oval biconvex film-coated tablets (dimension: 6.5 x 10.5 mm), debossed with 'C9CC' on one side and '90' on the other side.

[Nationally completed name] is available in PVC/PE/PVDC/Al blister packs of 14, 28 and 84 film-coated tablets.

Not all pack sizes are 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:

Denmark:	Cinacalcet Sandoz 30 mg filmovertrukne tabletter Cinacalcet Sandoz 60 mg filmovertrukne tabletter Cinacalcet Sandoz 90 mg filmovertrukne tabletter
Belgium:	Cinacalcet Sandoz 30 mg filmomhulde tabletten Cinacalcet Sandoz 60 mg filmomhulde tabletten Cinacalcet Sandoz 90 mg filmomhulde tabletten
Bulgaria:	Цинакалцет Сандоз 30 mg филмирани таблетки Цинакалцет Сандоз 60 mg филмирани таблетки Цинакалцет Сандоз 90 mg филмирани таблетки
Cyprus:	Cinacalcet Hydrochloride Sandoz
Czech Republic:	Cinacalcet Sandoz
Finland:	Cinacalcet Sandoz 30 mg kalvopäällysteiset tabletit. Cinacalcet Sandoz 60 mg kalvopäällysteiset tabletit. Cinacalcet Sandoz 90 mg kalvopäällysteiset tabletit.
France:	CINACALCET GNR 30 mg, comprimé pelliculé CINACALCET GNR 60 mg, comprimé pelliculé

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Germany:	CINACALCET GNR 90 mg, comprimé pelliculé Cinacalcet HEXAL 30 mg Filmtabletten Cinacalcet HEXAL 60 mg Filmtabletten Cinacalcet HEXAL 90 mg Filmtabletten
Greece:	CINACALCET/SANDOZ
Ireland:	Cinacalcet Rowex 30mg Film-coated tablets Cinacalcet Rowex 60mg Film-coated tablets Cinacalcet Rowex 90mg Film-coated tablets
Iceland:	Cinacalcet Sandoz 30 mg filmuhúðaðar töflur. Cinacalcet Sandoz 60 mg filmuhúðaðar töflur Cinacalcet Sandoz 90 mg filmuhúðaðar töflur
Italy:	Cinacalcet Sandoz
Lithuania:	Cinacalcet Sandoz 30 mg plėvele dengtos tabletės Cinacalcet Sandoz 60 mg plėvele dengtos tabletės Cinacalcet Sandoz 90 mg plėvele dengtos tabletės
Latvia:	Cinacalcet Sandoz 30 mg apvalkotās tabletes Cinacalcet Sandoz 60 mg apvalkotās tabletes Cinacalcet Sandoz 90 mg apvalkotās tabletes
Netherlands:	Cinacalcet Sandoz 30 mg, filmomhulde tabletten Cinacalcet Sandoz 60 mg, filmomhulde tabletten Cinacalcet Sandoz 90 mg, filmomhulde tabletten
Norway:	Cinacalcet Sandoz 30 mg filmdrasjerte tabletter. Cinacalcet Sandoz 60 mg filmdrasjerte tabletter. Cinacalcet Sandoz 90 mg filmdrasjerte tabletter
Poland :	Cinacalcet Sandoz
Romania:	Cinacalcet Sandoz 30 mg comprimate filmate Cinacalcet Sandoz 60 mg comprimate filmate Cinacalcet Sandoz 90 mg comprimate filmate
Slovenia:	Cinacalcet Lek 30 mg filmsko obložene tablete Cinacalcet Lek 60 mg filmsko obložene tablete Cinacalcet Lek 90 mg filmsko obložene tablete
Slovakia:	Cinacalcet Sandoz 30mg Cinacalcet Sandoz 60mg Cinacalcet Sandoz 90mg
Spain:	Cinacalcet Sandoz 30 mg comprimidos recubiertos con película EFG Cinacalcet Sandoz 60 mg comprimidos recubiertos con película EFG Cinacalcet Sandoz 90 mg comprimidos recubiertos con película EFG
Sweden:	Cinacalcet Sandoz 30 mg filmdragerade tabletter Cinacalcet Sandoz 60 mg filmdragerade tabletter Cinacalcet Sandoz 90 mg filmdragerade tabletter
United Kingdom:	Cinacalcet Sandoz 30 mg Film-coated Tablets

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Cincalcet Sandoz 60 mg Film-coated Tablets
Cincalcet Sandoz 90 mg Film-coated Tablets

This leaflet was last revised in {MM/YYYY}

[To be completed nationally]