15.02.2018: national AIC in NL (duplicate);
21.03.2018: approval var.01/G (RVG122007-122008-122009/IA/001/G) Type IA B.II.e.5.b. Deletion of a pack sizes, Type IAIN B.II.b.1.a addition of secondary packager (SCF).
11.10.2018: NL/H/l4457/001-003/MR with the national finalization of the MRP, en-common texts with national details were approved (DOC Generici declared that the product was never marketed in the Netherlands and commit that (new) Dutch product information will be submitted for approval before the product will be marketed in the Netherlands).
The PI have been updated, but not with substantial changes, therefore the approval date has not been changed.; NL/H/4457/IB/002/G 2x IB C.I.2.a + QRD

Package leaflet: Information for the patient

Cinacalcet DOC 30 mg, filmomhulde tabletten
Cinacalcet DOC 60 mg, filmomhulde tabletten
Cinacalcet DOC 90 mg, filmomhulde tabletten

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 [Product name] is and what it is used for

[Product 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).

[Product name] is used:

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

In primary and secondary hyperparathyroidism too much PTH is produced by the parathyroids 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 [Product name]

Do not take [Product name]:

- 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 you blood calcium levels.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking [Product name]

Before you start taking [Product 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.**

[Product name] reduces calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in patients 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 [product name].

Low calcium levels can have an effect on your heart rhythm. Tell your doctor if you experience an unusually fast or pounding heart beat, if you have heart rhythm problems, or if you take medicines known to cause heart rhythm problems, while taking [Product name].

For additional information see section 4.

During treatment with [Product name], tell your doctor:

- if you start or stop smoking, as this may affect the way [Product name] works.

Children and adolescents

Children under the age of 18 must not take [Product name]

Other medicines and [Product 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 [product name] together with etelcalcetide.

Tell your doctor if you are taking the following medicines.

Medicines such as these can affect how [Product 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).

[Product 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).

[Product name] with food and drink
[Product 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.

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

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

Driving and using machines
Dizziness and seizures have been reported by patients taking [Product name]. If you experience these side effects, do not drive or operate machinery.

3 How to take [Product 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 [Product name] you must take.

[Product 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.

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 [Product name] is 30 mg (one tablet) once per day.

If you are being treated for parathyroid cancer or primary hyperparathyroidism
The usual starting dose for [Product name] is 30 mg (one tablet) twice per day.

If you take more [Product name] than you should
If you take more [Product 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 [Product name]
Do not take a double dose to make up for a forgotten dose.

If you have forgotten a dose of [Product 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.

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 [Product 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 [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {Product 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 [Product name] contains

- The active substance is cinacalcet. Each tablet contains 30 60 90 mg cinacalcet.
- The other ingredients are: starch, pregelatinized (maize), cellulose, microcrystalline (E460), povidone (K-29/32), crospovidone (type A and B), magnesium stearate (E572), silica, colloidal anhydrous (tablet core); polyvinyl alcohol-partially hydrolyzed (E1203), titanium dioxide (E171), macrogol (L 4000), talc (E553b), FD&C Blue #2/Indigo carmine aluminum lake (E132), iron oxide yellow (E172) (tablet coating)

What [Product name] looks like and contents of the pack

[Product name] are green oval biconvex coated tablets (approximately 4.5 x 7 mm), debossed with C9CC on one side and 30 on the other side.
[Product name] are green oval biconvex coated tablets (approximately 5.5 x 9 mm), debossed with C9CC on one side and 60 on the other side.
[Product name] are green oval biconvex coated tablets (approximately 6.5 x 10.5 mm), debossed with C9CC on one side and 90 on the other side.

Cinacalcet is available in PVC/PE/PVDC/Al transparent blister packs with 30 mg, 60 mg or 90 mg film-coated tablets. Each blister pack contains 28 tablets in a carton.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen:
DOC Generici Srl,
Via Turati, 40
20121 Milan
Italië

Manufacturer(s)
Synthon Hispania S.L.
Castelló 1
Polígono Las Salinas
08830 Sant Boi de Llobregat
Spanje

Synthon s.r.o
Brněnska 32 /čp. 597
678 01 Blansko
Tsjechische Republiek

In het register ingeschreven onder:
Cinacalcet DOC 30 mg, filmomhulde tabletten: RVG 122007

Cinacalcet DOC 60 mg, filmomhulde tabletten: RVG 122008
Cinacalcet DOC 90 mg, filmomhulde tabletten: RVG 122009

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

The Netherland:	Cinacalcet DOC 30 mg, 60 mg, 90 mg, filmomhulde tabletten
Italy	CINACALCET DOC 30 mg, 60 mg, 90 mg, compresse rivestite con film

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2020