

Cinacalcet prescribing information sheet		
V2	Last reviewed May 2023	Review date: May 2026

Cinacalcet

Traffic light classification- Amber 2 Information sheet for Primary Care Prescribers

Licensed Indications

Cinacalcet is classified as Amber 2 for primary hyperparathyroidism (PHPT) in adults. In line with recommendations in [NICE NG132](#), it is recommended for people with primary hyperparathyroidism if surgery has been unsuccessful, is unsuitable or has been declined, and if their albumin adjusted calcium level is either:

- 2.85mmol/litre or above with symptoms of hypercalcaemia or
- 3.00mmol/litre or above with or without symptoms of hypercalcaemia.

Any exclusions

Cinacalcet is also licensed for

- Secondary hyperparathyroidism for adults and paediatric patients ≥ 3 years of age with end-stage renal disease (ESRD) on maintenance dialysis.
- Parathyroid carcinoma in adults.

These indications are excluded from the Amber 2 classification.

Patients prescribed cinacalcet by Primary Care must be over 18 years of age.

Therapeutic Summary

Cinacalcet is a calcimimetic agent which directly lowers parathyroid hormone (PTH) levels by increasing the sensitivity of the calcium sensing receptor to extracellular calcium. The reduction in PTH is associated with a concomitant decrease in serum calcium levels.

Medicines Initiation

Cinacalcet is to be initiated by the specialist in secondary care. The patient must be on a stable dose for at least 3 months before prescribing can be passed on to primary care.

Products available

Product	Strength	Cost for 28 tablets*
Cinacalcet	30mg	£8.68
Cinacalcet	60mg	£31.06
Cinacalcet	90mg	£46.59

*prices correct from Drug Tariff April 2023

Cinacalcet is also available as 1mg, 2.5mg and 5mg granules for opening. However, this formulation should not be prescribed in Primary Care.

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Dosages and route of administration

Cinacalcet tablets are for oral administration, to be taken with or shortly after food.

Maintenance doses of cinacalcet may be up to 90mg three to four times daily. However, it is anticipated that the majority of patients would be stabilised on no more than 30mg two to three times a day.

Duration of treatment

If effective, life-long treatment with cinacalcet will be necessary.

Monitoring Requirements and Responsibilities

Responsibility	Albumin adjusted serum calcium levels
Secondary care	Within one week of starting treatment or adjusting dosing.
Primary care	6 monthly for 2 years and then annually, unless clinical reason to test sooner. Lifelong.

The aim of treatment is to maintain adjusted Calcium level at between 2.50 and 2.80 mmol/l.

Explicit criteria for review and discontinuation of the medicine

Criteria for review	Management Advice
Symptoms of hypocalcaemia eg paraesthesias, myalgias, cramping, tetany and convulsions.	Check calcium level- see below for management if hypocalcaemia confirmed.
Albumin adjusted serum calcium levels decrease below 2.2mmol/l	Withhold cinacalcet. Recheck calcium after 1 week. Discuss with specialist as patient will likely require significant dose reduction.
Albumin adjusted serum calcium levels of 2.20 – 2.50 mmol/l	Seek specialist advice as patient will likely require dose reduction.
Albumin adjusted serum calcium levels of > 2.80 mmol/l	Check compliance; Seek specialist advice as patient will likely require dose increase.
Nausea and Vomiting	Usually transient- provide symptomatic relief. If persists discuss with specialist.
Any change to smoking status	Contact specialist for advice as dose adjustment may be required.

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.

Contraindications

Cinacalcet is contraindicated in patients with hypocalcaemia and those with sensitivities to the active substance or to any of the excipients.

Precautions

Precaution must be taken with patients who have a history of:

- Seizures (fits or convulsions) – significant reductions in serum calcium levels may lower the seizure threshold. Monitor calcium levels closely in those with a history of seizures.

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- Moderate to severe hepatic impairment- lower doses may be required and treatment should be closely monitored during dose titration and continued treatment.
- Heart failure and/or hypotension.
- Risk factors for QT prolongation eg Congenital long QT syndrome or those receiving medicinal products known to cause QT prolongation.
- Pregnancy and lactation- specialist advice required.

Clinically relevant medicine interactions and their management

Products known to reduce serum calcium (e.g. bisphosphonates, denosumab)- use with cinacalcet may result in an increased risk of hypocalcaemia. Patients taking cinacalcet should not be given etelcalcetide.

Medications known to cause QT-prolongation e.g. citalopram, quetiapine, amisulpride- use with caution.

Strong CYP34A inhibitors e.g. ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir / inducers e.g. rifampicin. – dose adjustments of cinacalcet may be required.

Smoking- Cinacalcet is metabolised in part by the enzyme CYP1A2. Smoking induces this enzyme, therefore dose adjustments may be necessary if a patient starts or stops smoking.

Medications metabolised by CYP2D6 e.g. flecainide, propafenone, metoprolol, desipramine, nortriptyline, clomipramine- Cinacalcet is a strong inhibitor of CYP2D6 therefore dose adjustments may be required.

For a full list of contraindications, precautions and drug interactions refer to the BNF/ product SPC.

Information given to patient

Advice to patient/carers

- To take cinacalcet with or shortly after food.
- To contact their doctor if they experience any spasms, twitches, muscles cramps, numbness or tingling in fingers, toes or around the mouth as this may indicate low calcium levels.
- To inform their doctor if they are stopping or starting to smoke as it may affect the way cinacalcet works.
- To counsel on the effects on driving and performance of skilled tasks as there is an increased risk of dizziness.

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Further advice and support – this information is not inclusive of all prescribing information

Summary of product characteristics via electronic Medicines Compendium ([eMC](#))
 British National Formulary: <https://bnf.nice.org.uk/>

**Sherwood Forest Hospitals NHS Foundation Trust
 Consultant endocrinologist, Kings Mill Hospital**

Patient Pathway Coordinators: 01623 622515 Ext: 3272

Specialist Contact Details (out of hours)

For Medical Professionals – Ring: 01623 622 515 and ask to speak to On call Endocrinologist

NUH

Consultant endocrinologist

via Gateway Number 0115 919 4477 ext 78993

Specialist Contact Details (out of hours)

For Medical Professionals – Ring: 0115 924 9924 and ask to speak to On call Endocrinologist

References:

Cinacalcet SPC accessed via www.medicines.org.uk/emc 26th April 2023.

[NICE NG132: Hyperparathyroidism \(primary\): diagnosis, assessment and initial management, May 2019](#)

Version Control- Cinacalcet information sheet		
Version	Date	Changes
2.	May 23	Full document review. Frequency of monitoring in Primary Care reduced, price update, advice about management of out of range results clarified.