

Cinacalcet (Mimpara®)
For the treatment of primary hyperparathyroidism
when parathyroidectomy is contraindicated or not clinically appropriate
Effective Shared Care Agreement

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details

Specialist:
 Address: _____

Email: _____

Contact number: _____

GP

Address: _____

Email: _____

Contact number: _____

Patient

Name: _____

Contact number: _____

Agreement to shared care, to be signed by GP and Specialist before prescribing is transferred to GP

Specialist
Signature: _____

Date: _____

GP
Signature: _____

Date: _____

Patient
Signature: _____

Date: _____

This Effective Shared Care Agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist.

If a specialist asks the GP to prescribe, the GP should reply to this request within 2 weeks

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment

- Discuss with the patient options for treatment and the suitability of Cinacalcet
- Discuss the potential benefits and side effects of treatment with the patient
- Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient. Consultant attaches copy of Shared Care Agreement (SCA)
- Undertake serum calcium check before treatment is initiated and within 1 week post initiation
- Commence treatment with cinacalcet and once patient is on a stable dose between visits, consider transfer of prescribing and monitoring to GP.
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Ensure this has been discussed with patient, and that patient has signed SCA form
- Regular follow-up of patient
- Communicate promptly with the GP when treatment is changed
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner

- To confirm, without delay, their agreement or otherwise to participate in shared care.
- To monitor side effects of treatment and seek advice from the specialist if necessary.
- To liaise with specialist regarding any complications of treatment or the discontinuation of treatment.
- To check for possible drug interactions when newly prescribing concurrent treatment.
- To monitor calcium levels every two-three months
- Report adverse events to the consultant and MHRA (via Yellow Card)

Communication

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Hospital Pharmacy Dept:				
Other:				

General information on Cinacalcet

Licensed Indication

Cinacalcet is indicated for the treatment of significant hypercalcaemia (calcium > 3.0mmol/l) due to Primary Hyperparathyroidism, when parathyroidectomy is contraindicated or not clinically appropriate.

Dosage and administration

The usual dose of cinacalcet is between 30-60mg twice daily. The calcium lowering effect is substantially present within two to three weeks (85-90%) after initiating therapy with 30mg twice daily. In patients whose serum calcium is not adequately controlled, the dose may be increased to 90mg twice daily. If adequate control of hypercalcaemia has not been achieved on 60mg of cinacalcet however, the specialist

should review the benefit of on-going treatment with cinacalcet and reconsider alternative treatment options. Cinacalcet should be taken with or after food once a day, preferably at the same time each day.

Contraindications

Cinacalcet is contraindicated in:

- Known hypersensitivity to the drug or any of the excipients
- Pregnancy
- Breast-feeding

Cautions

Cinacalcet should be used with caution in:

- Epilepsy (reduction of seizure threshold in some studies in patients with CKD, with seizure activity in 1.4% of patients with epilepsy on cinacalcet versus 0.4% of controls).
- Hepatic insufficiency
- Heart failure

Side effects

The most frequently reported adverse events are nausea and vomiting, rash, hypersensitivity, dizziness and myalgia. Isolated cases of hypotension, worsening heart failure and arrhythmia also reported.

Monitoring

Serum calcium should be checked before treatment and within 1 week post initiation of cinacalcet. Further review of serum calcium should occur every 2-3 months.

Drug Interactions¹

Caution is advised with substrates of CYP2D6 as levels and side-effects may be increased (e.g. **flecainide, metoprolol, tricyclic antidepressants**)

Caution is advised with potent inhibitors (e.g. **ketoconazole**) and inducers (e.g. **rifampicin**) of this enzyme.

Cinacalcet is also metabolised by CYP1A2 - cautious use of **ciprofloxacin** (CYP1A2 inhibitor) is advised. Smoking induces CYP1A2 and therefore dose adjustments may be required if the patient starts or stops smoking during cinacalcet treatment.

Cinacalcet possibly inhibits metabolism for **Tamoxifen** to active metabolite- avoid concomitant use.

There are numerous drug interactions and the Summary of Product Characteristics (www.medicines.org.uk) should be consulted both before treatment and when new drugs are introduced.

¹ BNF 70 September 2015-March 2016.