

## Summary of the risk management plan (RMP) for Cinacalcet Mylan (cinacalcet)

This is a summary of the risk management plan (RMP) for Cinacalcet Mylan, which details the measures to be taken in order to ensure that Cinacalcet Mylan is used as safely as possible. For more information on RMP summaries, see [here](#).

This RMP summary should be read in conjunction with the EPAR summary and the product information for Cinacalcet Mylan, which can be found on [Cinacalcet Mylan's EPAR page](#).

### Overview of disease epidemiology

Cinacalcet Mylan is used to treat hyperparathyroidism in patients with serious kidney disease. Hyperparathyroidism, a condition in which the parathyroid glands in the neck produce too much parathyroid hormone (PTH), develops early in chronic kidney disease, before dialysis is required. Consequently, most patients with chronic kidney disease stage 5 or end-stage renal disease have raised parathyroid hormone.

Cinacalcet Mylan is also used to reduce blood calcium levels in patients with parathyroid carcinoma (cancer of the parathyroid glands) or primary hyperparathyroidism (hyperparathyroidism that is not caused by any other condition). Parathyroid carcinoma has an estimated incidence of 2 cases per 10,000,000 persons/year in Europe. Primary hyperparathyroidism had an estimated incidence of 0.3% of the general population (3 out of 1000 person).

### Summary of treatment benefits

Cinacalcet Mylan is a generic medicine of Mimpara. Studies in people showed that Cinacalcet Mylan is bioequivalent to Mimpara, meaning that they both produce the same levels of the active substance in the body.

The benefits and risks of Cinacalcet Mylan are therefore taken as being the same as Mimpara's.

### Unknowns relating to treatment benefits

Cinacalcet is not been tested in pregnant women and it is not known whether cinacalcet passes into human milk. The use of cinacalcet in children and adolescents has not been established.

### Summary of safety concerns

#### *Important identified risks*

<b>Risk</b>	<b>What is known</b>	<b>Preventability</b>
Low calcium levels in blood (Hypocalcaemia)	Unusually fast or pounding heart beat (QT prolongation and ventricular arrhythmia), numbness	Patients experiencing these symptoms should talk to the doctor immediately. Patients should be

Risk	What is known	Preventability
	or tingling around the mouth, muscle aches or cramps, and seizures (fits) may be associated with low levels of calcium in blood.	monitored carefully for low blood calcium levels whilst being treated with cinacalcet. If calcium levels fall, the dose may need to be reduced or treatment interrupted.  Treatment with cinacalcet should not be started in patients with low blood calcium levels.
Seizures/convulsions (fits)	Patients who have had seizures in the past are at a higher risk of seizures whilst on treatment with cinacalcet. An overdose of Cinacalcet Mylan could also lead to seizures. Seizures can also occur when blood calcium levels are low.	Before starting to take Cinacalcet Mylan, patients should tell their doctors if they have ever had seizures. The doctors can then modify the treatment accordingly or closely monitor the patient during treatment.
Low blood pressure (hypotension) and/or worsening heart failure	After taking cinacalcet a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension).	The doctor may check patient's heart condition and blood pressure at regular intervals to make sure that patient's blood pressure does not become too low and that the heart failure does not worsen.
Allergic reactions including rash, hives or angioedema, a condition which includes signs such as swelling of the face, lips, mouth, tongue or throat and may cause difficulty in swallowing or breathing (Hypersensitivity reactions including rash, urticaria, and angioedema)	The following side effects are common (occurring in up to 1 patient in 10) with the use of cinacalcet: rash and allergic reactions (hypersensitivity) such as hives (urticaria) and swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing (angioedema).	Cinacalcet must not be used in patients who are allergic to cinacalcet or any other ingredient of this medicine.  Prescribers should be aware about the risk of possible allergic reaction in patients taking cinacalcet.
Unusual heart rhythm due to low level of calcium in the blood (QT prolongation and ventricular arrhythmias secondary to hypocalcaemia)	Cinacalcet use may induce unusually fast or pounding heart beat which may be associated with low levels of calcium in the blood.	Prescribers should be aware about the risk of unusually fast or pounding heart beat which may be associated with low levels of calcium in the blood in patients taking cinacalcet.

### **Important potential risks**

<b>Risk</b>	<b>What is known</b>
Broken or cracked bones (fractures)	Patients treated with cinacalcet for primary and secondary hyperparathyroidism are at risk of fractures due to loss of calcium in the bones, as calcium is important for bone strength.
Inflammation of the pancreas over a short period of time (acute pancreatitis)	Patients treated with cinacalcet may be at risk of inflammation of the pancreas. This is a serious problem with the following signs or symptoms: <ul style="list-style-type: none"><li>• severe upper stomach pain</li><li>• feeling sick (nausea)</li><li>• being sick (vomiting)</li></ul>
Possible liver problems due to medication (possible drug-related hepatic disorders)	Cinacalcet should be used with caution in patients with moderate to severe liver problems and treatment should be closely monitored during dose titration and continued treatment. Patients are advised to talk to their doctor pharmacist or nurse before taking Cinacalcet Mylan if they have had liver problems.
Nervous system disorders (excluding seizure)	Cinacalcet use may cause side effects such as dizziness, numbness or tingling sensation (paraesthesia) and headache.
Tumour-related effects (neoplastic events)	In a large, long-term study, patients who received cinacalcet had a higher rate of abnormal changes in body tissues (neoplasms) than patients who received placebo
Heart disorders	Cinacalcet use may cause side effects such as unusually fast or pounding heart beat which may be associated with low levels of calcium in the blood (QT prolongation and ventricular arrhythmia secondary to hypocalcaemia) The frequency of these side effects is not known.  Also, a few patients with heart failure experienced worsening of their condition and/or low blood pressure (hypotension).  Patients are advised to inform their doctor about previous or recent experience of heart failure.

### **Missing information**

<b>Risk</b>	<b>What is known</b>
Pregnant or breastfeeding women	Cinacalcet should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.  Following a careful benefit-risk assessment, a decision should be made to discontinue either breast-feeding or treatment with cinacalcet.
Use in children (paediatric patients)	Cinacalcet is not indicated for use in children and adolescents due to a lack of data on safety and efficacy.

## **Summary of risk minimisation measures by safety concern**

All medicines have a summary of product characteristics (SmPC) which provides physicians, pharmacists and other healthcare professionals with details on how to use the medicine, and also describes the risks and recommendations for minimising them. Information for patients is available in lay language in the package leaflet. The measures listed in these documents are known as 'routine risk minimisation measures'.

The SmPC and the package leaflet are part of the medicine's product information. The product information for Cinacalcet Mylan can be found on [Cinacalcet Mylan's EPAR page](#).

This medicine has no additional risk minimisation measures.

## **Planned post-authorisation development plan**

No studies planned.

## **Summary of changes to the risk management plan over time**

Not applicable

This summary was last updated in 10-2015.