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EPAR summary for the public

Cinacalcet Mylan

cinacalcet

This is a summary of the European public assessment report (EPAR) for Cinacalcet Mylan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Cinacalcet Mylan.

For practical information about using Cinacalcet Mylan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Cinacalcet Mylan and what is it used for?

Cinacalcet Mylan is a medicine used in adults and older patients to:

- treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products. Hyperparathyroidism is a condition in which the parathyroid glands in the neck produce too much parathyroid hormone (PTH), which can lead to high levels of calcium in the blood, bone and joint pain and deformities of the arms and legs. 'Secondary' means that it is caused by another condition. Cinacalcet Mylan can be used as part of treatment including phosphate binders or vitamin D;
- reduce hypercalcaemia (high blood calcium levels) in patients with parathyroid carcinoma (cancer of the parathyroid glands) or with primary hyperparathyroidism who cannot have their parathyroid glands removed or when the doctor thinks that their removal is not appropriate. 'Primary' means that the hyperparathyroidism is not caused by any other condition.

Cinacalcet Mylan contains the active substance cinacalcet and is a 'generic medicine'. This means that Cinacalcet Mylan is similar to a 'reference medicine' already authorised in the European Union (EU). The reference medicine for Cinacalcet Mylan is Mimpara.

For more information on generic medicines, see the question-and-answer document here.

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How is Cinacalcet Mylan used?

Cinacalcet Mylan is available as 30, 60 and 90 mg tablets. In secondary hyperparathyroidism, the recommended starting dose for adults is 30 mg once a day. The dose is adjusted every two to four weeks, according to the patient's PTH levels, up to a maximum of 180 mg once a day. PTH levels should be assessed at least 12 hours after dosing and one to four weeks after each dose adjustment of Cinacalcet Mylan. Blood calcium levels should be measured frequently, and within one week of each dose adjustment of Cinacalcet Mylan. Once a maintenance dose has been established, calcium levels should be measured monthly and PTH levels should be measured every one to three months.

In patients with parathyroid carcinoma or primary hyperparathyroidism, the recommended starting dose of Cinacalcet Mylan for adults is 30 mg twice a day. The dose of Cinacalcet Mylan should be increased every two to four weeks up to 90 mg three or four times a day as necessary to reduce blood calcium to normal levels.

Cinacalcet Mylan is taken with food or shortly after a meal. The medicine can only be obtained with a prescription.

How does Cinacalcet Mylan work?

The active substance in Cinacalcet Mylan, cinacalcet, works by increasing the sensitivity of the calcium-sensing receptors on the parathyroid glands that regulate PTH secretion. By increasing the sensitivity of these receptors, cinacalcet leads to a reduction in the production of PTH by the parathyroid glands. The reduction in PTH levels leads to a decrease in blood calcium levels.

How has Cinacalcet Mylan been studied?

Because Cinacalcet Mylan is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Mimpara. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Cinacalcet Mylan?

Because Cinacalcet Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Cinacalcet Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Cinacalcet Mylan has been shown to have comparable quality and to be bioequivalent to Mimpara. Therefore, the CHMP's view was that, as for Mimpara, the benefit outweighs the identified risk. The Committee recommended that Cinacalcet Mylan be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Cinacalcet Mylan?

A risk management plan has been developed to ensure that Cinacalcet Mylan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Cinacalcet Mylan, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Cinacalcet Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Cinacalcet Mylan on 19 November 2015.

The full EPAR and risk management plan summary for Cinacalcet Mylan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Cinacalcet Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 11-2015.