



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Cinacalcet Viatris¹ (*cinacalcet*)

An overview of Cinacalcet Viatris and why it is authorised in the EU

What is Cinacalcet Viatris and what is it used for?

Cinacalcet Viatris is a medicine used to:

- treat secondary hyperparathyroidism (overactive parathyroid glands) in adults with serious kidney disease who need dialysis (to clear their blood of waste products);
- reduce hypercalcaemia (high blood calcium levels) in adults with cancer of the parathyroid glands or with primary hyperparathyroidism when the parathyroid glands cannot be removed.

In hyperparathyroidism, the parathyroid glands in the neck produce too much parathyroid hormone (PTH), which can lead to high levels of blood calcium, bone and joint pain and deformities of the arms and legs. 'Secondary' means that it is caused by another condition (serious kidney disease) while 'primary' means there is no other cause.

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

For more information on generic medicines, see the question-and-answer document [here](#).

How is Cinacalcet Viatris used?

Cinacalcet Viatris is available as tablets, to be taken with food or shortly after a meal.

In patients with secondary hyperparathyroidism, the medicine is taken once a day and the dose is adjusted according to the patient's PTH and calcium levels.

In patients with hypercalcaemia who also have parathyroid gland cancer or primary hyperparathyroidism, the medicine is taken twice a day. The dose is increased and taken up to 3 or 4 times a day as necessary to reduce blood calcium to normal levels.

¹ Previously known as Cinacalcet Mylan.



The medicine can only be obtained with a prescription.

For more information about using Cinacalcet Viatris, see the package leaflet or contact your doctor or pharmacist.

How does Cinacalcet Viatris work?

The active substance in Cinacalcet Viatris, cinacalcet, is a calcimimetic agent. This means that it mimics the action of calcium in the body. 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 Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Mimpara, and do not need to be repeated for Cinacalcet Viatris.

As for every medicine, the company provided studies on the quality of Cinacalcet Viatris. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Cinacalcet Viatris?

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

Why is Cinacalcet Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Cinacalcet Viatris has been shown to have comparable quality and to be bioequivalent to Mimpara. Therefore, the Agency's view was that, as for Mimpara, the benefits outweigh the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Cinacalcet Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Mimpara also apply to Cinacalcet Viatris where appropriate.

As for all medicines, data on the use of Cinacalcet Viatris are continuously monitored. Suspected side effects reported with Cinacalcet Viatris are carefully evaluated and any necessary action taken to protect patients.

Other information about Cinacalcet Viatris

Cinacalcet Mylan received a marketing authorisation valid throughout the EU on 19 November 2015.

The name of the medicine was changed to Cinacalcet Viatris on 15 October 2024.

Further information on Cinacalcet Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cinacalcet-viatris. Information on the reference medicine can also be found on the Agency's website.

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