



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/65298/2020  
EMA/H/C/005236

## Cinacalcet Accordpharma (*cinacalcet*)

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

### What is Cinacalcet Accordpharma and what is it used for?

Cinacalcet Accordpharma is a medicine used to treat:

- secondary hyperparathyroidism (overactive parathyroid glands) in adults and children aged 3 years and older with serious kidney disease who need dialysis (to clear their blood of waste products);
- 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 Accordpharma contains the active substance cinacalcet and is a 'generic medicine'. This means that Cinacalcet Accordpharma contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Mimpara. For more information on generic medicines, see the question-and-answer document [here](#).

### How is Cinacalcet Accordpharma used?

Cinacalcet Accordpharma is available as 30, 60 and 90 mg tablets, to be taken with food or shortly after a meal.

In patients with secondary hyperparathyroidism, the recommended starting dose for adults is 30 mg once a day, while in children the daily starting dose depends on the child's weight. The dose is adjusted, according to the patient's PTH and calcium levels. In younger patients requiring less than 30 mg once a day, other cinacalcet products should be used that allow a lower dose to be given.

In patients with hypercalcaemia who also have parathyroid gland cancer or primary hyperparathyroidism, the recommended starting dose of Cinacalcet Accordpharma in adults is 30 mg twice a day. The dose should be increased every 2 to 4 weeks up to 90 mg three or four times a day as necessary to reduce blood calcium to normal levels.

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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The medicine can only be obtained with a prescription. For more information about using Cinacalcet Accordpharma, see the package leaflet or contact your doctor or pharmacist.

### **How does Cinacalcet Accordpharma work?**

The active substance in Cinacalcet Accordpharma, 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 also leads to a decrease in blood calcium levels.

### **How has Cinacalcet Accordpharma 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 Accordpharma.

As for every medicine, the company provided studies on the quality of Cinacalcet Accordpharma. The company also carried out a study 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 Accordpharma?**

Because Cinacalcet Accordpharma 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 Accordpharma authorised in the EU?**

The European Medicines Agency concluded that, in accordance with EU requirements, Cinacalcet Accordpharma 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 of Cinacalcet Accordpharma 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 Accordpharma?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Cinacalcet Accordpharma have been included in the summary of product characteristics and the package leaflet.

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

### **Other information about Cinacalcet Accordpharma**

Cinacalcet Accordpharma received a marketing authorisation valid throughout the EU on 3 April 2020.

Further information on Cinacalcet Accordpharma can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/cinacalcet-accordpharma](http://ema.europa.eu/medicines/human/EPAR/cinacalcet-accordpharma). Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2020.