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EPAR summary for the public

Mimpara

cinacalcet

This is a summary of the European public assessment report (EPAR) for Mimpara. 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 Mimpara.

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

What is Mimpara and what is it used for?

Mimpara 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.

Mimpara contains the active substance cinacalcet.

How is Mimpara used?

Mimpara is available as tablets and as granules in capsules, to be taken with food or shortly after a meal. The capsules should not be swallowed whole but should be opened and the granules sprinkled in food or liquid.

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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 patients with hypercalcaemia who also have parathyroid gland cancer or primary hyperparathyroidism, the recommended starting dose of Mimpara for adults is 30 mg twice a day. The dose of Mimpara 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.

The medicine can only be obtained with a prescription. For more information see the package leaflet.

How does Mimpara work?

The active substance in Mimpara, 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 parathyroid hormone 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.

What benefits of Mimpara have been shown during the studies?

Secondary hyperparathyroidism

Mimpara has been compared with placebo (a dummy treatment) in three main studies involving 1,136 adults with secondary hyperparathyroidism who were on dialysis because they had a serious kidney disease. The main measure of effectiveness was the number of patients who had a parathyroid hormone level below 250 micrograms per litre after 6 months.

In these studies, about 40% of the patients taking Mimpara had parathyroid hormone levels below 250 micrograms per litre, compared with about 6% of those taking placebo. Mimpara brought about a 42% reduction in average PTH levels compared with an increase of 8% in patients taking placebo.

In children, Mimpara was compared with placebo in a study involving 43 children aged 6 to 18 years with serious kidney disease. The main measure of effectiveness was the reduction of PTH levels by 30%. In this study, 55% (12 out of 22) children given Mimpara achieved a 30% reduction of PTH levels, compared with 19% (4 out of 21) children given placebo.

Parathyroid gland cancer or primary hyperparathyroidism

Mimpara has been studied in a study involving 46 patients with hypercalcaemia, including 29 with parathyroid cancer, and 17 with primary hyperparathyroidism who could not have their parathyroid glands removed or in whom surgery to remove the parathyroid glands was not effective. The main measure of effectiveness was the number of patients whose blood calcium levels fell by more than 1 mg per decilitre by the time a maintenance dose had been found (between two and 16 weeks after the start of the study). The study continued for over three years. Mimpara produced a decrease in blood calcium of more than 1 mg/dl in 62% of the cancer patients (18 out of 29) and in 88% of the patients with primary hyperparathyroidism (15 out of 17).

A further three studies compared Mimpara with placebo in a total of 136 patients with primary hyperparathyroidism over up to a year. Of these, 45 went on to a fourth, long-term study looking at

the effectiveness of Mimpara over a total of almost six years. The results supported the use of Mimpara for hypercalcaemia in patients with primary hyperparathyroidism.

What are the risks associated with Mimpara?

The most common side effects with Mimpara (in more than 1 patient in 10) are nausea (feeling sick) and vomiting.

Mimpara must not be used in patients with hypocalcaemia (low blood calcium levels). For the full list of side effects and restrictions of Mimpara, see the package leaflet.

Why is Mimpara approved?

Studies showed that Mimpara was effective in both adults and children at reducing levels of parathyroid hormone in patients with secondary hyperparathyroidism who were undergoing dialysis for kidney disease. In addition, Mimpara reduced high calcium levels in the majority of patients with parathyroid gland cancer or primary hyperparathyroidism.

With regard to the medicine's safety, side effects seen in patients are considered manageable. The European Medicines Agency therefore concluded that Mimpara's benefits outweigh the risks and recommended that it be given marketing authorisation.

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

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

Other information about Mimpara

The European Commission granted a marketing authorisation valid throughout the European Union for Mimpara on 22 October 2004.

The full EPAR for Mimpara 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 Mimpara, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.