European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PARAREG

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. . If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Parareg?
Parareg is a medicine containing the active substance cinacalcet. It is available as light green oval tablets (30, 60 or 90 mg).

What is Parareg used for?
Parareg is used in adults and elderly patients:

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

The medicine can only be obtained with a prescription.

How is Parareg used?
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 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 Parareg. Blood calcium levels should be measured frequently, and within one week of each dose adjustment of Parareg. 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 Parareg for adults is 30 mg twice a day. The dose of Parareg 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.

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Parareg is taken with food or shortly after a meal.

How does Parareg work?
The active substance in Parareg, 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 also leads to a decrease in blood calcium levels.

How has Parareg been studied?
Parareg has been studied in three main studies involving 1,136 dialysis patients with serious kidney disease. Parareg was compared with placebo (a dummy treatment). The studies lasted for six months. The main measure of effectiveness was the number of patients who had a PTH level below 250 micrograms per litre at the end of the study.
Parareg has also been studied in a study involving 46 patients with hypercalcaemia, including 29 with parathyroid carcinoma 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 who had a reduction in blood calcium levels of 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. A further three studies compared the effectiveness of Parareg and placebo in a total of 186 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 Parareg over a total of almost six years.

What benefit has Parareg shown during the studies?
In dialysis patients with serious kidney disease, about 40% of the patients taking Parareg had PTH levels below 250 micrograms/l at the end of the study, compared with about 6% of those taking placebo. Parareg brought about a 42% reduction in PTH levels compared with an increase of 8% in patients taking placebo.
Parareg 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). The results of the additional studies supported the use of Parareg for hypercalcaemia in patients with primary hyperparathyroidism.

What is the risk associated with Parareg?
The most common side effects with Parareg in secondary hyperparathyroidism (seen in more than 1 patient in 10) are nausea (feeling sick) and vomiting. In patients with parathyroid carcinoma or primary hyperparathyroidism, the side effects are similar to those seen in patients with long-standing kidney disease - the most frequent side effects are nausea and vomiting. For the full list of all side effects reported with Parareg, see the Package Leaflet.
Parareg should not be used in people who may be hypersensitive (allergic) to cinacalcet or any of the other ingredients.

Why has Parareg been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Parareg's benefits are greater than its risks for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy, and for the reduction of hypercalcaemia in patients with parathyroid carcinoma or primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels but in whom parathyroidectomy is not clinically appropriate or is contraindicated. The Committee recommended that Parareg be given marketing authorisation.

Other information about Parareg:
The European Commission granted a marketing authorisation valid throughout the European Union for Parareg on 22 October 2004. The marketing authorisation holder is Dompé Biotec S.p.A.

The full EPAR for Parareg is available here.

This summary was last updated in 06-2008.