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EPAR summary for the public

Parsabiv

etelcalcetide

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

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

What is Parsabiv and what is it used for?

Parsabiv is a medicine used to reduce the levels of parathyroid hormone in adults who have high levels of this hormone because of their long-term kidney disease (secondary hyperparathyroidism). Parathyroid hormone is produced by the parathyroid glands in the neck and regulates calcium and phosphate levels. High levels of parathyroid hormone can cause loss of calcium from the bones, bone pain and fractures, and heart and circulation problems.

Parsabiv is used in patients on haemodialysis (a technique for removing waste products from the blood using a blood filtration machine). It contains the active substance etelcalcetide.

How is Parsabiv used?

Parsabiv is available as a solution for injection. Treatment is started at a dose of 5 mg three times a week and the dose is then adjusted according to the patient's parathyroid hormone level or calcium level. It is given at the end of a haemodialysis session into the line that leads back from the dialysis machine to the patient's vein. In some circumstances, it can be given by injection into a vein.

Parsabiv can only be obtained with a prescription. For further information, see the package leaflet.

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How does Parsabiv work?

When cells in the parathyroid gland detect high levels of calcium in the blood, they reduce the amount of parathyroid hormone entering the blood. The active substance in Parsabiv, etelcalcetide, is a calcimimetic. This means that it mimics the action of calcium on these cells and in this way, it reduces the parathyroid hormone levels in the blood. Reduced parathyroid hormone decreases the levels of calcium in the blood.

What benefits of Parsabiv have been shown in studies?

Parsabiv has been investigated in three main studies involving 1,706 patients on haemodialysis who had long-term kidney disease and secondary hyperparathyroidism. The first two studies compared Parsabiv with placebo (a dummy treatment), and the third study compared it with cinacalcet, another calcimimetic medicine. In all three studies, Parsabiv was given for 26 weeks. The main measure of effectiveness was a reduction in parathyroid hormone by more than 30% after at least 20 weeks of treatment.

In the first two studies, Parsabiv was effective in 75% (380 out of 509) of patients compared with 9% (46 out of 514) of patients given placebo. In the third study, Parsabiv was found to be at least as effective as cinacalcet: in 68% (232 out of 340) patients given Parsabiv compared with 58% (198 out of 343) patients given cinacalcet.

What are the risks associated with Parsabiv?

The most common side effects with Parsabiv (which may affect more than 1 in 10 people) are low calcium level in the blood, muscle spasm, diarrhoea, nausea (feeling sick) and vomiting.

Parsabiv must not be started if the patient's blood calcium level is below the normal range. For the full list of Parsabiv's side effects and restrictions, see the package leaflet.

Why is Parsabiv approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Parsabiv's benefits are greater than its risks and recommended that it be approved for use in the EU. The medicine has been found effective for reducing parathyroid hormone in the blood in patients with kidney disease being treated with haemodialysis and its side effects are those expected of a calcimimetic substance.

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

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

Other information about Parsabiv

The European Commission granted a marketing authorisation valid throughout the European Union for Parsabiv on 11 November 2016.

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

This summary was last updated in 11-2016.