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EPAR summary for the public

Renagel

sevelamer hydrochloride

This is a summary of the European public assessment report (EPAR) for Renagel. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Renagel.

What is Renagel?

Renagel is a medicine that contains the active substance sevelamer hydrochloride. It is available as tablets (400 and 800 mg).

What is Renagel used for?

Renagel is used to control hyperphosphataemia (high blood phosphate levels) in adults on dialysis (a blood clearance technique used in patients with kidney disease). It can be used in patients undergoing haemodialysis (dialysis using a blood filtration machine) or peritoneal dialysis (where fluid is pumped into the abdomen and an internal body membrane filters the blood). Renagel should be used with other treatments such as calcium or vitamin D supplements to control the development of bone disease.

The medicine can only be obtained with a prescription.

How is Renagel used?

The recommended starting dose of Renagel depends on the level of phosphate in the blood and ranges from 800 to 1,600 mg three times a day. The dose of Renagel should be adjusted to ensure that the blood phosphate level stays below 1.76 mmol/l. Patients should take Renagel tablets whole with meals and stick to their prescribed diets.

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How does Renagel work?

Patients with long-term kidney disease cannot eliminate phosphate from their bodies. This leads to hyperphosphataemia, which, in the long term, can cause complications such as heart and bone disease. The active substance in Renagel, sevelamer hydrochloride, is a phosphate binder. When taken with meals, it attaches to phosphate from food within the gut, preventing it from being absorbed into the body. This helps to reduce the phosphate levels in the blood.

How has Renagel been studied?

In haemodialysis, Renagel has been studied in two short-term studies lasting eight weeks and one longer study lasting 44 weeks. The first study compared Renagel with calcium acetate (another phosphate-lowering medicine) in 84 patients. The second, which did not compare Renagel with any other medicines, included 172 patients. The longer study looked at the use of Renagel in 192 patients, the majority of whom had taken Renagel in previous studies.

In peritoneal dialysis, there has been one study comparing Renagel with calcium acetate in 143 patients over 12 weeks.

In all of the studies, the main measure of effectiveness was the change in blood phosphate levels between the start and the end of treatment.

What benefit has Renagel shown during the studies?

Renagel produced a significant decrease in serum phosphate in all of the studies.

In the comparative study of patients undergoing haemodialysis, there was an average fall of 0.65 mmol/l over the eight weeks of Renagel treatment, compared with 0.68 mmol/l when the patients were taking calcium acetate. Patients taking Renagel had a similar fall in phosphate levels in the second study. In the third, there was an average fall of 0.71 mmol/l over 44 weeks.

In the study of patients undergoing peritoneal dialysis, the patients receiving Renagel had similar falls in phosphate as the patients receiving calcium acetate (0.52 and 0.58 mmol/l, respectively).

What is the risk associated with Renagel?

The most common side effects with Renagel (seen in more than 1 patient in 10) are nausea (feeling sick) and vomiting. For the full list of all side effects reported with Renagel, see the package leaflet.

Renagel must not be used in people with hypophosphataemia (low blood phosphate levels) or with bowel obstruction (a blockage in the gut).

Why has Renagel been approved?

The CHMP decided that Renagel's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Renagel is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Renagel, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Renagel

The European Commission granted a marketing authorisation valid throughout the European Union for Renagel on 28 January 2000.

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

This summary was last updated in 10-2014.