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EPAR summary for the public

BindRen

colestilan

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

What is BindRen?

BindRen is a medicine that contains the active substance colestilan. It is available as tablets (1 g) and as granules (sachets containing 2 or 3 g).

What is BindRen used for?

BindRen is used to control hyperphosphataemia (high blood phosphate levels) in adults with long-term kidney disease who are on dialysis (a blood clearance technique). It is used in patients on haemodialysis (using a blood filtration machine) or peritoneal dialysis (where fluid is pumped into the abdomen and an internal body membrane filters the blood).

The medicine can only be obtained with a prescription.

How is BindRen used?

The recommended starting dose of BindRen is 6 to 9 g per day, taken in three equally divided doses together with or immediately after meals. The dose of BindRen should be adjusted every two to three weeks to a maximum of 15 g per day to reach an acceptable level of phosphate in the blood, which should then be monitored regularly. Patients should keep to their prescribed low phosphate diets.

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How does BindRen work?

Patients with severe 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 BindRen, colestilan, is a phosphate binder. When taken with meals, colestilan 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 BindRen been studied?

The effects of BindRen were first tested in experimental models before being studied in humans.

BindRen was investigated in two main studies involving 273 adults with long-term kidney disease and hyperphosphataemia. All patients were on dialysis and received BindRen for three months.

A third main study involving 642 patients compared the effects of giving BindRen at various doses with placebo (a dummy treatment) for three months.

All studies looked at the change in the average amount of phosphate in the blood after three months.

What benefit has BindRen shown during the studies?

The first two studies showed that BindRen was effective at controlling blood phosphate levels in patients with long-term kidney disease who were on dialysis. In the first study, an average dose of 11.5 g of BindRen reduced the blood phosphate level by 0.36 mmol/l on average after three months. Similarly in the second study, an average dose of 13.1 g of BindRen resulted in a reduction of the blood phosphate level by 0.50 mmol/l on average after three months.

The third study also showed that BindRen was more effective than placebo when used at doses of 6, 9, 12 and 15 g/day: compared with placebo, the reduction in blood phosphate levels seen with BindRen was 0.16, 0.21, 0.19 and 0.37 mmol/l respectively.

What is the risk associated with BindRen?

In clinical trials, around 3 in 10 patients experienced at least one side effect. The most serious reported side effects with BindRen were gastrointestinal haemorrhage (bleeding in the stomach and gut) and constipation. The most frequently reported side effects were nausea (feeling sick), dyspepsia (heartburn) and vomiting. For the full list of all side effects reported with BindRen, see the package leaflet.

BindRen must not be used in people who are hypersensitive (allergic) to colestilan or any of the other ingredients. It must not be used in people with bowel obstruction (a blockage in the gut).

Why has BindRen been approved?

The CHMP noted that treatment with BindRen has a beneficial effect in lowering phosphate levels. There were no major safety concerns and the overall safety profile was similar to that of other phosphate binders, as the side effects affected mainly the gut and resolved by themselves. The CHMP decided that BindRen's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about BindRen

The European Commission granted a marketing authorisation valid throughout the European Union for BindRen on 21 January 2013.

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

This summary was last updated in 01-2013.