26 September 2012
EMA/555461/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

BindRen

colestilan

On 26 September 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product BindRen, 1000 mg, 2000 mg, 3000 mg, film-coated tablet intended for the treatment of hyperphosphataemia in adult patients with Chronic Kidney Disease (CKD) Stage 5 receiving haemodialysis or peritoneal dialysis. The applicant for this medicinal product is Mitsubishi Pharma Europe Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of BindRen is colestilan, a drug for the treatment of hyperkalemia and hyperphosphatemia (V03AE). The product is not absorbed from the human gastrointestinal (GI) tract and is not metabolised during transit of the GI tract. In the treatment of hyperphosphataemia, it acts in the GI tract as a non-calcium, non-metallic phosphate binder.

The benefits with BindRen are its ability to lower the serum phosphorus concentration. BindRen also binds bile acids, thereby lowering the serum LDL-cholesterol concentration. Changes in the bile acid pool in the gastrointestinal tract have also been observed to lower serum glucose. BindRen may also bind uric acid in the gastrointestinal tract. The most common side effects are gastrointestinal haemorrhage (uncommon) and constipation (common). The most frequently reported adverse reactions were nausea, dyspepsia and vomiting (all common). The frequency of adverse reactions increased with dose.

A pharmacovigilance plan for BindRen will be implemented as part of the marketing authorisation.

The approved indication is: "*BindRen is indicated for the treatment of hyperphosphataemia in adult patients with Chronic Kidney Disease (CKD) Stage 5 receiving haemodialysis or peritoneal dialysis.*" It is proposed that BindRen be prescribed by physicians experienced in the treatment of hyperphosphataemia. The recommended starting dose is 6-9 g per day (2-3 g three times daily). Patients previously on other phosphate binders who are switched to BindRen should start taking 6-9 g per day (2-3 g three times daily).

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for BindRen and therefore recommends the granting of the marketing authorisation.