EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2015
EMA/CHMP/453873/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fexeric

Ferric citrate coordination complex

On 23 Jul 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fexeric, intended for the treatment of hyperphosphataemia in adult patients with chronic kidney disease. The applicant for this medicinal product is Keryx Biopharma UK Ltd.

Fexeric will be available as film-coated tablets containing 210mg of ferric iron in 1g of ferric citrate coordination complex. The active substance of Fexeric is ferric citrate coordination complex (ATC code: V03AE). Phosphate binding takes place by ligand exchange in the gastrointestinal tract. Serum phosphorus levels are reduced as a consequence of the reduced dietary phosphate absorption.

The benefits with Fexeric are its ability to reduce serum phosphorus in patients with chronic kidney disease, as shown in the pivotal study where patients treated with Fexeric had a significant decrease in serum phosphorus compared with patients treated with placebo. The most common side effects are gastrointestinal disorders.

The full indication is: "Fexeric is indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease (CKD)".

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.

[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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