27 March 2025
EMA/CHMP/82632/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xoanacyl

ferric citrate coordination complex

On 27 March 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xoanacyl, intended for the treatment of concomitant hyperphosphataemia and iron deficiency in adults with chronic kidney disease (CKD).

The applicant for this medicinal product is Averoa SAS.

Xoanacyl will be available as 1 g film-coated tablets (containing 210 mg of ferric iron). The active substance of Xoanacyl is ferric citrate coordination complex (ATC code: V03AE08). The ferric iron in Xoanacyl is reduced to the ferrous form in the gastrointestinal tract, where it is subsequently transported through enterocytes into the blood and incorporated into haemoglobin. The non-absorbed part binds to dietary phosphate, forming an insoluble compound that is excreted through stools, thereby reducing absorption of phosphate and lowering serum phosphorus levels.

Xoanacyl has been studied in two clinical trials in patients with CKD who are not dialysis dependant. The benefits are an increase in transferrin saturation and haemoglobin levels, as well as a decrease in serum phosphorus levels, compared with placebo. Additionally, in a controlled clinical study in patients with CKD who are dialysis dependent, Xoanacyl was found to be non-inferior to sevelamer carbonate in reducing serum phosphorus levels. The most common side effects with Xoanacyl are diarrhoea, abdominal pain and nausea.

The full indication is:

> Xoanacyl is indicated for the treatment of concomitant elevated serum phosphorous and iron deficiency in adult patients with chronic kidney disease (CKD).

Treatment with Xoanacyl should be initiated under the supervision of a physician experienced in the management of patients with renal disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union

[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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languages after the marketing authorisation has been granted by the European Commission.