17 December 2015
EMA/765141/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Feraccru

ferric maltol

On 17 December 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 Feraccru, intended for the treatment of iron deficiency anaemia in adults with inflammatory bowel disease. The applicant for this medicinal product is Iron Therapeutics (UK) Ltd.

Feraccru will be available as 30 mg hard capsules. The active substance of Feraccru is ferric maltol, an oral trivalent iron preparation (ATC code: B03AB) which provides iron for uptake across the intestinal wall and transfer to the iron transport and storage proteins in the body (transferrin and ferritin, respectively).

The benefits with Feraccru are its ability to increase haemoglobin levels in patients. The most common side effects are abdominal pain (including in the upper abdomen), flatulence, constipation, abdominal discomfort/ distension, diarrhoea and nausea.

The full indication is:

"Feraccru is indicated in adults for the treatment of iron deficiency anaemia (IDA) in patients with inflammatory bowel disease (IBD) (see section 5.1)."

It is proposed that Feraccru be prescribed by physicians experienced in the treatment of iron deficiency anaemia.

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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