22 February 2018
EMA/84262/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Feraccru

ferric maltol

On 22 February 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Feraccru. The marketing authorisation holder for this medicinal product is Shield TX (UK) Ltd.

The CHMP adopted an extension to the existing indication as follows[2]:

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

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] Removed text as strikethrough

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact