22 June 2023
EMA/286712/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Mircera

methoxy polyethylene glycol-epoetin beta

On 22 June 2023, 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 Mircera. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to an existing indication for use in paediatric patients. For information, the full indications for Mircera will be as follows:[2]

> Treatment of **symptomatic** anaemia associated with chronic kidney disease (CKD) in adult patients (see section 5.1).
>
> **Treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in paediatric patients from 3 months to less than 18 years of age who are converting from another erythropoietin stimulating agent (ESA) after their haemoglobin level was stabilised with the previous ESA (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] New text in bold

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