22 February 2024
EMA/65369/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Reblozyl

Luspatercept

On 22 February 2024, 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 Reblozyl. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

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

> Reblozyl is indicated for the treatment of ~~**adult patients with**~~ transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS) ~~with ring sideroblasts, who had an unsatisfactory response to or are ineligible for erythropoietin-based therapy~~ (see section 5.1).

For information, the full indications for Reblozyl will be as follows:

> Reblozyl is indicated in adults for the treatment of transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS) (see section 5.1).
>
> Reblozyl is indicated in adults for the treatment of anaemia associated with transfusion dependent and non-transfusion dependent beta thalassaemia (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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union