15 December 2022
EMA/CHMP/931343/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Hemlibra

emicizumab

On 15 December 2022, 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 Hemlibra. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to an existing indication to include routine prophylaxis of bleeding episodes in patients with haemophilia A without factor VIII inhibitors who have moderate disease with severe bleeding phenotype. For information, the full indications for Hemlibra will be as follows:[2]

> Hemlibra is indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency):
>
> - with factor VIII inhibitors
> - without factor VIII inhibitors who have:
>   - severe disease (FVIII < 1%)
>   - **moderate disease (FVIII ≥ 1% and ≤ 5%) with severe bleeding phenotype.**
>
> Hemlibra can be used in all age groups.

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

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