



31 January 2019
EMA/CHMP/848842/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Hemlibra emicizumab

On 31 January 2019, 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 the existing indication as follows:²

“Hemlibra is proposed for the treatment for routine prophylaxis of bleeding episodes in patients with

- haemophilia A (**congenital factor VIII deficiency**) with factor VIII inhibitors.
- **severe haemophilia A (congenital factor VIII deficiency, FVIII<1 %) without FVIII inhibitors.**

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

