



26 March 2026
EMADOC-1700519818-2999788
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Hympavzi

marstacimab

On 26 March 2026, 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 Hympavzi. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted changes to the existing indication as follows:²

Hympavzi is indicated for routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with:

- ~~severe hH~~ **Haemophilia A (congenital factor VIII deficiency, FVIII < 1%):**
 - ~~W~~ **Without factor VIII inhibitors who have severe disease (FVIII < 1%), or**
 - **With factor VIII inhibitors**
- ~~severe hH~~ **Haemophilia B (congenital factor IX deficiency, FIX < 1%):**
 - ~~W~~ **Without factor IX inhibitors who have severe disease (FIX < 1%), or**
 - **With factor IX inhibitors**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summary 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, removed text as strikethrough

