23 July 2026
EMA/542815/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Jivi

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On 23 July 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 Jivi. The marketing authorisation holder for this medicinal product is Bayer AG.

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

> Treatment and prophylaxis of bleeding in ~~previously treated~~ patients ≥ 7 years of age with haemophilia A (congenital factor VIII deficiency).

For information, the full indication for Jivi will now be:

> Treatment and prophylaxis of bleeding in patients ≥ 7 years of age with haemophilia A (congenital factor VIII deficiency).

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] Deleted text in strikethrough.

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