

12 October 2023 EMA/448949/2023 Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Veyvondi

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On 12 October 2023, 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 Veyvondi. The marketing authorisation holder for this medicinal product is Baxalta Innovations GmbH.

The CHMP adopted an extension to include prophylaxis against haemorrhage in patients with von Willebrand disease (VWD). For information, the full indication will therefore be as follows:²

Prevention and treatment of haemorrhage or surgical bleeding in adults (age 18 years and older) with von Willebrand disease (VWD), when desmopressin (DDAVP) treatment alone is ineffective or contraindicated.

VEYVONDI is indicated in adults (age 18 and older) with von Willebrand Disease (VWD), when desmopressin (DDAVP) treatment alone is ineffective or not indicated, for the

- Treatment of haemorrhage and surgical bleeding-
- Prevention of surgical bleeding.

VEYVONDI should not be used in the treatment of haemophilia A.

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.



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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, removed text as strikethrough