



25 April 2024  
EMA/167452/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Altuvoct

## efanesoctocog alfa

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Altuvoct<sup>2</sup>, intended for the prevention and treatment of bleeding in patients with haemophilia A caused by factor VIII deficiency.

The applicant for this medicinal product is Swedish Orphan Biovitrum AB (publ).

Altuvoct will be available as 250 IU, 500 IU, 750 IU, 1000 IU, 2000 IU, 3000 IU and 4000 IU powder and solvent for solution for injection. The active substance of Altuvoct is efanesoctocog alfa, a recombinant human factor VIII which replaces the missing coagulation factor VIII needed for effective haemostasis (ATC code: B02BD02).

The benefits of Altuvoct are its ability to prevent and control bleeding when used on demand and during surgical procedures, as seen in clinical trials in adults and children with haemophilia A. The most common side effects with Altuvoct are headache, vomiting, eczema, rash, urticaria, arthralgia, pain in extremity, back pain and pyrexia.

The full indication is:

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). Altuvoct can be used for all age groups.

Altuvoct treatment should be under the supervision of a physician experienced in the treatment of haemophilia.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

