23 July 2015
EMA/CHMP/471356/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Obizur

susoctocog alfa

On 23 July 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Obizur, intended for the treatment of bleeding episodes in patients with acquired haemophilia caused by antibodies to factor VIII.

Obizur was designated as an orphan medicinal product on 20 September 2010. The applicant for this medicinal product is Baxalta Innovations GmbH.

Obizur will be available as a powder (500 Units/vial) and solvent for solution for injection. The active substance of Obizur is susoctocog alfa, a porcine recombinant factor VIII (ATC code: B02BD14). It acts to stop bleeding by forming a complex with activated clotting factor IX, and thereby accelerating the conversion of clotting factor X to activated clotting factor X. Activated clotting factor X ultimately converts prothrombin into thrombin which then converts fibrinogen into fibrin and thus forms a blood clot.

The benefits with Obizur are its ability to stop or reduce bleeding with clinical improvement. The most common side effect is positive test for inhibitory antibodies against porcine factor VIII.

The full indication is:

"Treatment of bleeding episodes in patients with acquired haemophilia caused by antibodies to Factor VIII.

Obizur is indicated in adults."

It is proposed that Obizur be prescribed by physicians 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

[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] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2015. Reproduction is authorised provided the source is acknowledged.

made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.