9 November 2017
EMA/CHMP/708455/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Adynovi

rurioctocog alfa pegol

On 9 November 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Adynovi, intended for the treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia A (congenital factor VIII deficiency). The applicant for this medicinal product is Baxalta Innovations GmbH.

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

The benefits with Adynovi are its ability to prevent and control bleeding when used on demand and during surgical procedures, as seen in clinical trials in adult and paediatric patients with haemophilia A. The most common side effects are headache, diarrhoea, nausea and rash.

The full indication is: “treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia A (congenital factor VIII deficiency)”. It is proposed that Adynovi 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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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

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