28 June 2018
EMA/CHMP/324506/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Veyvondi

vonicog alfa

On 28 June 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Veyvondi, intended for the treatment of von Willebrand disease. Veyvondi was designated as an orphan medicinal product on 26 November 2010. The applicant for this medicinal product is Baxalta Innovations GmbH.

Veyvondi will be available as a powder and solvent for solution for injection (650 IU and 1300 IU). The active substance of Veyvondi is vonicog alfa, a recombinant human von Willebrand factor which behaves in the same way as endogenous von Willebrand factor (ATC code: B02BD10).

The benefits with Veyvondi are its ability to re-establish platelet adhesion to the endothelium at the site of blood vessel damage and to correct associated factor VIII deficiency. The most common side effects are dizziness, vertigo, dysgeusia, tremor, tachycardia, deep venous thrombosis, hypertension, hot flush, vomiting, nausea, generalised pruritus, chest discomfort, infusion site paraesthesia, electrocardiogram T wave inversion and increased heart rate.

The full indication is:

"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."

It is proposed that Veyvondi be prescribed by physicians experienced in the treatment of haemostatic disorders.

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

[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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