



30 May 2013
EMA/CHMP/301621/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Voncento

Human coagulation factor VIII, human Von Willebrand factor

On 30 May 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Voncento by CSL Behring GmbH. This recommendation will now be forwarded to the European Commission, which will issue a legally binding decision.

Voncento is recommended to be used for the prevention and treatment of bleeding in patients with haemophilia A and Von Willebrand disease (two inherited bleeding disorders).

The indications recommended by the CHMP are as follows:

“Von Willebrand disease (VWD): Treatment of haemorrhage or prevention and treatment of surgical bleeding in patients with Von Willebrand disease, when desmopressin treatment alone is ineffective or contraindicated.

Haemophilia A (congenital factor VIII deficiency): Prophylaxis and treatment of bleeding in patients with haemophilia A.”

The active substances in Voncento are human coagulation factor VIII and human Von Willebrand factor, substances that help the blood to clot, also known as antihaemorrhagics. Patients with haemophilia A lack factor VIII and patients with Von Willebrand disease lack Von Willebrand factor, which leads to bleeding disorders. Voncento is used to correct the deficiency by replacing the missing coagulation factors, giving temporary control of the bleeding disorder.

Voncento will be available as a powder and solvent for solution for injection or infusion in three strengths (250 IU / 600 IU, 500 IU / 1200 IU, and 1000 IU / 2400 IU). It will only be obtained with a prescription and treatment should be supervised by a doctor who has experience in the treatment of haemostatic disorders (bleeding disorders).

The Agency’s Committee for Medicinal Products for Human Use (CHMP) decided that Voncento’s benefits are greater than its risks following the assessment of two main studies, one study

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.



investigating the effects of Voncento in 81 patients with haemophilia A, and one investigating the effects of Voncento in 22 patients with Von Willebrand disease. Voncento was effective in preventing the occurrence of bleeding events in patients with severe haemophilia A and in stopping bleeding in patients with severe Von Willebrand disease. When bleeding events did occur in haemophilia A patients on prophylaxis, Voncento was effective in treating these events. Voncento was also effective in the prevention and treatment of bleeding in relation to surgery.

Regarding its safety, side effects were generally mild to moderate. The most common side effects are hypersensitivity or allergic reactions, thromboembolic events, pyrexia, headache, dysgeusia and abnormal liver function test levels. Furthermore patients may develop inhibitors to factor VIII and Von Willebrand factor.

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.