EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 June 2015
EMA/CHMP/420571/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Voncento

human coagulation factor VIII / human von Willebrand factor

On 25 June 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Voncento. The marketing authorisation holder for this medicinal product is CSL Behring GmbH.

The CHMP adopted an extension to an existing indication as follows[2]:
"**Prophylaxis and t**~~T~~reatment of haemorrhage or ~~prevention and treatment of~~ surgical bleeding in patients with VWD, when desmopressin (DDAVP) treatment alone is ineffective or contraindicated."

For information, the full indications for Voncento will be as follows:

"von Willebrand disease (VWD)

Prophylaxis and treatment of haemorrhage or surgical bleeding in patients with VWD, when desmopressin (DDAVP) treatment alone is ineffective or contraindicated.

Haemophilia A (congenital FVIII deficiency)

Prophylaxis and treatment of bleeding in patients with haemophilia A."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] New text in bold, removed text as strikethrough

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