



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2014
EMA/CHMP/279317/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Nuwiq

simoctocog alfa

On 22 May 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nuwiq, 250/500/1000/2000 IU, powder and solvent for solution for injection intended for treatment and prophylaxis of bleeding in paediatric and adult patients with haemophilia A (congenital factor VIII deficiency). The applicant for this medicinal product is Octapharma AB. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Nuwiq is simoctocog alfa, a recombinant blood coagulation factor VIII (B02BD02) - a replacement therapy to increase plasma levels of factor VIII, thereby temporarily enabling a correction of the factor VIII deficiency and correction of the bleeding tendencies.

The benefit with Nuwiq in terms of prevention and treatment of bleedings and haemostatic efficacy for surgical procedures was studied in 3 pivotal trials; study GENA-01 in 22 adolescent and adult subjects where overall, 94.4% of the bleeding episodes (BEs) were treated on-demand with excellent or good efficacy and a large majority of BEs required only 1 infusion; study GENA-08 investigated prophylaxis of bleeding events and the treatment of break-through bleeds in 32 adults, where the mean bleeding rates per patient during the prophylactic treatment period were 0.188/month for all types of bleeds. In study GENA-03 in 59 paediatric subjects between 2 and 11 years of age, the mean rate of all BEs in prophylaxis was 0.338 BEs/month; the monthly rate of all BEs was lower in patients aged 2 to 5 than in those aged 6 to 12 years (0.213 BEs/month and 0.459 BEs/month, respectively). In this study 68.6% of break-through bleeds were treated with one infusion and 81.3% with one or 2 infusions.

No side effects were commonly reported in the safety database of 135 previously treated patients. The immunogenicity of Nuwiq was evaluated in clinical trials in 135 previously treated patients with severe haemophilia A (74 adult and 61 paediatric patients). None of the patients developed inhibitors.

A pharmacovigilance plan for Nuwiq will be implemented as part of the marketing authorisation.

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.



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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Nuwiq and therefore recommends the granting of the marketing authorisation.