



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 January 2014
EMA/CHMP/21116/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

NovoThirteen catridecacog

On 23 January 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product NovoThirteen. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to an indication as follows:

"Long term prophylactic treatment of bleeding in adult and paediatric patients with congenital factor XIII A-subunit deficiency".

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

¹ Summaries of opinion are published without prejudice to the Commission Decision.

