



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/CHMP/385004/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

NovoThirteen catridecacog

On 23 July 2020, 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 NovoThirteen. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP adopted an extension to the existing indication as follows:²

Long term prophylaxis~~isetic treatment~~ of bleeding in patients with congenital factor XIII A-subunit deficiency. **Treatment of breakthrough bleeding episodes during regular prophylaxis.**
NovoThirteen can be used for all age groups.

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 shown in bold; removed text as strikethrough**

