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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): efanesoctocog alfa

Procedure No. PSUSA/00011062/202508

Period covered by the PSUR: 23 February 2025 to 22 August 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for efanesoctocog alfa, the scientific conclusions of PRAC are as follows:

In view of available data on risk from the literature, spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between efanesoctocog alfa and Factor VIII inhibition is at least a reasonable possibility. Accordingly, the PRAC concludes that the product information of products containing efanesoctocog alfa should be amended.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for efanesoctocog alfa the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing efanesoctocog alfa is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.