19 June 2025
EMADOC-1700519818-2223305
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): andexanet alfa

Procedure No. PSUSA/00010764/202410

Period covered by the PSUR: 6 months to 25 October 2024

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Scientific conclusions

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

In view of available data on the interaction between andexanet alfa and heparin from case reports, and in view of a plausible mechanism of action, the PRAC agreed that the interaction between andexanet alfa and heparin should be supplemented with further examples.

The PRAC concluded that the product information of products containing andexanet alfa should be amended accordingly.

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 andexanet alfa the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing andexanet 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.