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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): amivantamab

Procedure No. PSUSA/00010977/202411

Period covered by the PSUR: 21 May 2024 to 20 November 2024

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Scientific conclusions

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

In view of available data on skin ulcer from clinical trials, the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between amivantamab and skin ulcer is at least a reasonable possibility. The PRAC concluded that the product information of products containing amivantamab 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 amivantamab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing amivantamab 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.