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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): vosoritide

Procedure No. PSUSA/00010952/202508

Period covered by the PSUR:
1 year to 25 August 2025

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Scientific conclusions

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

In view of available data on the increase in frequency of the known adverse drug reaction "hypertrichosis" based on review of cumulative cases in clinical studies and spontaneous reports, the PRAC concluded that the product information of products containing vosoritide 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 vosoritide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing vosoritide 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.