25 April 2024
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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. EMEA/H/C/PSUSA/00010952/202308

Period covered by the PSUR:
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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 risk of hypertrichosis from clinical trials and spontaneous reports including cases with a close temporal relationship and with no alternative explanation, although, there is no data on a biological mechanism, the PRAC considers a causal relationship between vosoritide and hypertrichosis at least reasonable. 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.