21 March 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): voxelotor

Procedure No. EMEA/H/C/PSUSA/00010983/202308

Period covered by the PSUR: 14/02/2023 To: 13/08/2023

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Scientific conclusions

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

In view of available data on risks from clinical trials and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between voxelotor and *pruritus* as well as between voxelotor and *angioedema* (including Lip swelling, Swelling of eyelid, Face edema, and Periorbital swelling) is at least a reasonable possibility. The PRAC concluded that the product information of products containing voxelotor 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 voxelotor the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing voxelotor 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.