25 July 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): berotralstat

Procedure No. EMEA/H/C/PSUSA/00010930/202312

Period covered by the PSUR: 3 December 2022 to: 2 December 2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for berotralstat, the scientific conclusions of PRAC are as follows:

In view of available data on nausea from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between berotralstat and nausea is at least a reasonable possibility. The PRAC concluded that the product information of products containing berotralstat 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

On the basis of the scientific conclusions for berotralstat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing berotralstat is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.