19 September 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): osilodrostat

Procedure No. EMEA/H/C/PSUSA/00010820/202401

Period covered by the PSUR: 08 January 2023 To: 08 January 2024

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Scientific conclusions

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

In view of available data on sustained cortisol reduction after interruption from the literature, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between osilodrostat and sustained cortisol reduction after withdrawal is at least a reasonable possibility. The PRAC concluded that the product information of products containing osilodrostat should be amended accordingly to reflect this new aspect of hypocortisolism in section 4.4.

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 osilodrostat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing osilodrostat 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.