



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2022
EMA/129314/2023
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/00010820/202201

Period covered by the PSUR: 08 January 2021 to 08 January 2022



Scientific conclusions

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

In view of available data on myalgia and arthralgia from clinical trials and spontaneous reports, including in some cases a close temporal relationship and a positive de-challenge, and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between osilodrostat and myalgia and arthralgia is at least a reasonable possibility. The PRAC concluded that the product information of products containing osilodrostat should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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.