30 January 2025
EMA/21709/2025
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): roxadustat

Procedure No. EMEA/H/C/PSUSA/00010955/202406

Period covered by the PSUR: 17/12/2023 To: 16/06/2024

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Scientific conclusions

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

In view of available data on Thrombocytopenia from clinical trial(s), the literature, 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 Rapporteur considers a causal relationship between roxadustat and Thrombocytopenia is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing roxadustat 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 roxadustat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing roxadustat 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.