30 September 2022
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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): roxadustat

Procedure No. EMEA/H/C/PSUSA/00010955/202112

Period covered by the PSUR: 17/06/2021 To: 16/12/2021

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Scientific conclusions

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

In view of available data on Secondary Hypothyroidism from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between roxadustat and Secondary Hypothyroidism is at least a reasonable possibility. The PRAC concluded that the product information of products containing roxadustat 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 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.