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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. PSUSA/00010955/202412

Period covered by the PSUR:
1 year to 16 December 2024

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Annex IV

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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 ischemic central nervous system vascular conditions from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive dechallenge and rechallenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between roxadustat and cerebral infarction is at least a reasonable possibility. The PRAC concluded that the product information of products containing roxadustat should be amended accordingly. Furthermore, based on the expressed concerns of the MAH that current information presented in the PL on thrombocytopenia may suggest that the symptoms listed in the section 4 may affect up to 1 in 10 people, the PRAC concluded that the product information of products containing roxadustat should be amended to avoid this misinterpretation.

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.