25 April 2024
EMA/249668/2024
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): maralixibat

Procedure No. EMEA/H/C/PSUSA/00011032/202309

Period covered by the PSUR: 28/03/2023 To: 28/09/2023

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Scientific conclusions

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

Based on available data on increased transaminases activity from clinical trials and spontaneous reports, including 15 cases with a close temporal relationship, positive de-challenge, and re-challenge, the PRAC considers that a causal relationship between maralixibat and ALT increased and AST increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing maralixibat should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for the recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for maralixibat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing maralixibat 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.