19 September 2024
EMA/440110/2024
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): odevixibat

Procedure No. EMEA/H/C/PSUSA/00010949/202401

Period covered by the PSUR: 14/07/2023 To: 14/01/2024

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Scientific conclusions

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

In view of available data on risks from clinical trials and spontaneous reports, the PRAC considers a causal relationship between odevixibat, and ALT increased, and AST increased are at least a reasonable possibility. The PRAC concluded that the product information of products containing odevixibat 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 odevixibat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing odevixibat 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.