12 October 2023
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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): upadacitinib

Procedure No. EMEA/H/C/PSUSA/00010823/202302

Period covered by the PSUR: 16 August 2022 to 15 February 2023

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Scientific conclusions

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

In view of available data on hypoglycaemia in patients treated for diabetes from finding in the literature, spontaneous reports including in some cases a close temporal relationship, positive de-challenge and cases where anti-diabetic therapy was discontinued or dose reduced, in view of a plausible mechanism of action and potential class effect the PRAC considers a causal relationship between upadacitinib and hypoglycaemia in patients treated for diabetes is at least a reasonable possibility. The PRAC concluded that the product information of products containing upadacitinib 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 upadacitinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing upadacitinib 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.