EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 March 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): upadacitinib

Procedure No. EMEA/H/C/PSUSA/00010823/202108

Period covered by the PSUR: 16 February 2021 to 15 August 2021

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Scientific conclusions

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

In view of available data on urinary tract infections from clinical trial and spontaneous reports including cases with a close temporal relationship, a positive de-challenge and/or rechallege and in view of a plausible mechanism of action, the PRAC considers a causal relationship between upadacitinib and urinary tract infection is established. The PRAC concluded that the product information of upadacitinib 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 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.