EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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. PSUSA/00010823/202508

Period covered by the PSUR: 1 year to 15 August 2025

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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 semen discolouration from clinical trial(s) and spontaneous reports including, in 6 cases a positive rechallenge and, in 3 cases a positive dechallenge, the PRAC considers that a causal relationship between upadacitinib and semen discolouration 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.