



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2025
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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/00010823/202408

Period covered by the PSUR: 16 February 2024 to 15 August 2024



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 retinal vein occlusion, cases reported with at least a reasonable possibility of causal relationship between the event of retinal vein occlusion and upadacitinib treatment, seriousness of the condition, plausible mechanism of action as well as a potential class effect, the PRAC concluded that the product information of 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.