21 March 2024
EMA/246084/2024
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): upadacitinib

Procedure No. EMEA/H/C/PSUSA/00010823/202308

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

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 the available data on vertigo from spontaneous reports including in the majority of cases a close temporal relationship, 18 cases with positive de-challenge and 1 case with positive re-challenge and potential class effect, the PRAC considers that a causal relationship between upadacitinib and vertigo is established. The PRAC concluded that the product information of products containing upadacitinib should be amended accordingly.

In view of the available data on dizziness from spontaneous reports including cases with close temporal relationship, 59 cases with positive de-challenge and 8 case with positive re-challenge and potential class effect, the PRAC considers that a causal relationship between upadacitinib and dizziness is established. The PRAC concluded that the product information of products containing upadacitinib should be amended accordingly.

Available data on cases of tuberculosis reported from clinical trials and spontaneous sources suggest that important risk factor for development of tuberculosis was previous medical history of tuberculosis or exposure to tuberculosis. Therefore, it is recommended to amend wording in additional risk minimisation measures (HCP Educational Guide and Patient card) to strengthen the warning to HCPs and patients.

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.