25 April 2025
EMA/128458/2025
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): abrocitinib

Procedure No. EMEA/H/C/PSUSA/00010976/202409

Period covered by the PSUR: 8 March 2024 to 7 September 2024

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 for abrocitinib, the scientific conclusions of PRAC are as follows:

In view of available data on neutropenia, two cases reported with positive dechallenge and rechallenge as well as two additional reports with positive dechallenge together with clinical trial data and data from non-clinical trials where effect on neutrophil count was observed in rats, and potential class effect, the PRAC concluded that the product information of abrocitinib 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

On the basis of the scientific conclusions for abrocitinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing abrocitinib is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.