17 October 2024
EMA/42489/2025
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): pemetrexed

Procedure No. EMEA/H/C/PSUSA/00002330/202402

Period covered by the PSUR: 05/02/2021 To: 04/02/2024

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Scientific conclusions

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

In view of available data on the pharmacokinetics of pemetrexed and considering *in vitro* studies indicated that pemetrexed is actively secreted by organic anion transporter 3 (OAT3) and IC50 values for proton pump inhibitors, the PRAC considers a drug-drug interaction between proton pump inhibitors and pemetrexed is at least a reasonable possibility. The PRAC concluded that the product information of products containing pemetrexed 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 pemetrexed the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pemetrexed 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.