



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2024
EMA/40344/2025
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): esomeprazole

Procedure No. EMEA/H/C/PSUSA/00001269/202403

Period covered by the PSUR: 11/03/2021 To: 10/03/2024



Scientific conclusions

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

In view of available data on Drug reaction with eosinophilia and systemic symptoms (DRESS) from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between esomeprazole and DRESS is at least a reasonable possibility. SCARs other than DRESS are already included in 4.8 of the SmPC. Due to the severity of these side effects, they should be included into the proposed warning in 4.4. of the SmPC and the package leaflet accordingly. The PRAC concluded that the product information of products containing esomeprazole 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 esomeprazole the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing esomeprazole 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.