30 January 2025
EMA/70695/2025
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): ozanimod

Procedure No. EMEA/H/C/PSUSA/00010852/202405

Period covered by the PSUR: 20 May 2023 To: 19 May 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(s) for ozanimod, the scientific conclusions of PRAC are as follows:

In view of available data on Immune Reconstitution Inflammatory syndrome (IRIS syndrome) from the literature and in view of a plausible mechanism of action, the PRAC considers a causal relationship between ozanimod and IRIS is at least a reasonable possibility. The PRAC concluded that the product information of products containing ozanimod 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 ozanimod the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ozanimod 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.