30 May 2024
EMA/352161/2024
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): leflunomide

Procedure No. EMEA/H/C/PSUSA/00001837/202309

Period covered by the PSUR: 11 September 2020 to 10 September 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 leflunomide, the scientific conclusions of PRAC are as follows:

In view of the available data on impaired wound healing after surgery, from an observational study, the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a warning on impaired wound healing after surgery is needed. The PRAC concluded that the product information of products containing leflunomide 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 leflunomide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing leflunomide 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.