EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
EMA/691366/2019
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): erenumab

Procedure No. EMEA/H/C/PSUSA/00010699/201905

Period covered by the PSUR: 16/11/2018 To: 16/05/2019

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 erenumab, the scientific conclusions of CHMP are as follows:

Based on a review performed by the marketing authorisation holder on cases of serious hypersensitivity in association with erenumab use, a warning regarding hypersensitivity reactions is included in section 4.4 of the SmPC. In addition, section 4.8 is updated to include anaphylaxis and angioedema as undesirable effects. Package leaflet is updated accordingly.

Based on review performed by the marketing authorisation holder on cases of medication errors, the update to the instructions of use of the pre-filled syringe and pre-filled pen are warranted to minimise the risk of fingersticks and other medication errors.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for erenumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing erenumab 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.