EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/00010699/201811

Period covered by the PSUR: 17 May 2018 to 16 November 2018

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Scientific conclusions

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

There were 117 cases with 130 adverse events of hypersensitivity in the MAH's global safety database. 114 cases were received from postmarketing sources and 3 from clinical trials. The evidence suggested that there is a causal relationship with hypersensitivity leading to rash and/or edema and/or urticaria with the administration of erenumab. Based on this the PRAC considers that hypersensitivity reactions including rash, swelling/oedema and urticaria should be added as new adverse drug reactions in section 4.8 of the SmPC, and in the package leaflet.

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.