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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/00010699/201911

Period covered by the PSUR: 17 May 2019 To 16 November 2019

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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:

In view of available data on the cases of serious constipation from spontaneous reports, further characterisation of constipation events in the Summary of Product Characteristics is warranted.

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.