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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): fremanezumab

Procedure No. EMEA/H/C/PSUSA/00010758/202003

Period covered by the PSUR: From: 14/03/2019 To: 13/09/2019

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Scientific conclusions

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

In view of available data from clinical trials and spontaneous reports, the PRAC considers that a causal relationship between fremanezumab and hypersensitivity reactions, including urticaria, pruritus, rash and swelling/oedema is at least a reasonable possibility and the product information should be amended accordingly.

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 fremanezumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fremanezumab 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.