14 November 2024
EMA/514030/2024
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): ocrelizumab

Procedure No. EMEA/H/C/PSUSA/00010662/202403

Period covered by the PSUR: 28 March 2021 To: 27 March 2024

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Scientific conclusions

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

In the view of available data not raising concerns on an increased risk on adverse pregnancy outcomes in women exposed to ocrelizumab within 3 months prior to the last menstrual period and the available information on pharmacokinetics of ocrelizumab including half-terminal life of 26 days, the PRAC concluded that the product information of products containing ocrelizumab 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 ocrelizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ocrelizumab 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.