21 March 2024
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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): anifrolumab

Procedure No. EMEA/H/C/PSUSA/00010980/202307

Period covered by the PSUR: 30 January 2023 to 29 July 2023

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Scientific conclusions

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

In view of available post-marketing data on arthralgia, including 11 cases with close temporal relationship and the causality with anifrolumab is considered at least possible, and another 16 cases with a time to onset within 14 days. In addition, two cases with positive rechallenge have been reported including the French trigger case for which the causal relationship is considered probable. Overall, these cases provide sufficient evidence to support a causal relationship between anifrolumab and arthralgia. The PRAC concluded that the product information of products containing anifrolumab 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 anifrolumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing anifrolumab 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.