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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): ixazomib

Procedure No. EMEA/H/C/PSUSA/00010535/202311

Period covered by the PSUR:
19/05/2023 To: 19/11/2023

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Scientific conclusions

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

In view of available data on arthralgia and pyrexia from clinical trials, in which arthralgia and pyrexia has been reported at a ≥ 5% higher rate in patients treated with ixazomib monotherapy as compared with placebo, the PRAC Rapporteur considers a causal relationship between ixazomib and these events is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing ixazomib 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 ixazomib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ixazomib 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.