25 January 2024
EMA/150850/2024
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): ixazomib

Procedure No. EMEA/H/C/PSUSA/00010535/202305

Period covered by the PSUR: 19/11/2022 To: 19/05/2023

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Scientific conclusions

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

In view of available data on Toxic epidermal necrolysis (TEN) from spontaneous reports including 6 cases with a close temporal relationship, and in view of Steven Johnson syndrome (SJS) being labelled already, the PRAC Rapporteur considers a causal relationship between ixazomib and TEN to be at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing ixazomib should be amended accordingly. (Note that the PRAC rapporteur has suggested some changes to the text originally proposed by the MAH.) Further justification on the proposed frequency is asked for (RSI).

In view of available data on anaphylactic reaction and angioedema from clinical trials and spontaneous reports including 23 cases with a close temporal relationship and 10 cases with positive dechallenge, 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.