25 June 2020
EMA/395194/2020
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/00010535/201911

Period covered by the PSUR: 18 November 2018 – 18 November 2019

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ixazomib, the scientific conclusions of CHMP are as follows:
In view of available data on thrombotic microangiopathy from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between ixazomib and thrombotic microangiopathy is at least a reasonable possibility. The PRAC therefore recommends that the product information of products containing ixazomib 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 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.