27 June 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): ibrutinib

Procedure No. EMEA/H/C/PSUSA/00010301/202311

Period covered by the PSUR:
13/11/2022 To: 12/11/2023

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Scientific conclusions

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

In view of available data on cutaneous vasculitis from the literature, and spontaneous reports including cases with positive de-challenge and re-challenge, the PRAC Rapporteur considers a causal relationship between ibrutinib and cutaneous vasculitis is at least a reasonable possibility.
The PRAC Rapporteur concluded that the product information of products containing ibrutinib 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 ibrutinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ibrutinib 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.