Amsterdam, 18 September 2025
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): pirtobrutinib

Procedure No. EMEA/H/C/PSUSA/00000155/202501

Period covered by the PSUR:
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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for pirtobrutinib, the scientific conclusions of PRAC are as follows:
In view of available data on pirtobrutinib from clinical trials and spontaneous reports, including cases with a close temporal relationship, including positive de-challenges and re-challenges (of which one case had multiple positive rechallenges), the PRAC considers a causal relationship between pirtobrutinib and hepatic enzyme increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing pirtobrutinib 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 pirtobrutinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pirtobrutinib 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.