22 June 2023
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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/00010301/202211

Period covered by the PSUR: 13 November 2021 to 12 November 2022

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

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

In view of available data on Acute kidney injury, which includes observed disproportionality from clinical trials, available number of spontaneous cases with two cases reporting both positive dechallenge and rechallenge, additional cases described in literature and plausible mechanism via VEGF inhibition also described in literature, the PRAC considers causal relationship between ibrutinib and Acute kidney injury to be at least reasonable possibility.

In view of available data on Pyogenic granuloma from the literature, and spontaneous reports including in four cases a positive de-challenge and in view of a suggested mechanism of action through off-target influence of ibrutinib, the PRAC considers a causal relationship between ibrutinib and Pyogenic granuloma is at least a reasonable possibility.

The PRAC concluded that the product information of products containing ibrutinib 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 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.