15 October 2020
EMA/58304/2021
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): bosutinib

Procedure No. EMEA/H/C/PSUSA/00010073/202003

Period covered by the PSUR: 4 March 2019 – 3 March 2020

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Scientific conclusions

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

In view of available data on photosensitivity from spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, a medically confirmed skin biopsy confirming a photosensitivity reaction and a medically confirmed photosensitivity reaction by a significant UVA photo test, which was assessed as related to bosutinib, the PRAC Rapporteur considers that a causal relationship between bosutinib and photosensitivity is established. The PRAC Rapporteur concluded that the product information of products containing bosutinib 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 bosutinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bosutinib 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.