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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): rucaparib

Procedure No. EMEA/H/C/PSUSA/00010694/202012

Period covered by the PSUR: 20 June 2020 To: 19 December 2020

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Scientific conclusions

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

In view of available data on hypersensitivity reactions from clinical trial(s) and spontaneous reports including in some cases a close temporal relationship and a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between rucaparib and hypersensitivity reactions, such as oedema of the face, lips or eyes, is at least a reasonable possibility. The PRAC concluded that the product information of products containing rucaparib 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 rucaparib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rucaparib 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.