EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): capecitabine

Procedure No. EMEA/H/C/PSUSA/00000531/201804

Period covered by the PSUR: 30 April 2015 – 29 April 2018

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Scientific conclusions

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

During this PSUR period, 4 fatal cases of drug-drug interaction between brivudine and capecitabine were reported. To further minimise the risk of this potentially fatal interaction, a warning regarding this interaction should be added to section 4.4 of the SmPC and the existing contra-indication and drug-drug interaction information should be amended in sections 4.3 and 4.5 of the SmPC. Furthermore, the information in the product information should focus on brivudine and any reference concerning the non EU authorised sorivudine should be deleted.

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 capecitabine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing capecitabine 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.