30 January 2025
EMA/151502/2025
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): capecitabine

Procedure No. EMEA/H/C/PSUSA/00000531/202404

Period covered by the PSUR: 30 April 2021 to 29 April 2024

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Scientific conclusions

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

In view of available data from the literature showing that impaired kidney function is associated with increased uracil levels in blood, that could lead to a false diagnosis of DPD deficiency and subsequently to underdosing of capecitabine, the PRAC concluded that the product information of products containing capecitabine 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 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.