24 February 2022
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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): cabazitaxel

Procedure No. EMEA/H/C/PSUSA/00000476/202106

Period covered by the PSUR: 17 December 2019 to 17June 2021

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Scientific conclusions

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

In view of available data on nail disorder, gastrointestinal haemorrhage, ileus, gastritis, colitis, and gastrointestinal perforation, from clinical trials (TROPIC, PROSELICA, CARD) and spontaneous reports, the PRAC considers a causal relationship between cabazitaxel and these adverse reactions is at least a reasonable possibility and recommends to specify appropriate frequencies in the product information. The PRAC concluded that the product information of products containing cabazitaxel 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 cabazitaxel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cabazitaxel 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.