15 December 2022
EMA/93554/2023
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): tucatinib

Procedure No. EMEA/H/C/PSUSA/00010918/202204

Period covered by the PSUR: 16 October 2021 to 16 April 2022

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Scientific conclusions

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

In view of available data on nausea and vomiting from clinical trial(s) and spontaneous reports, the PRAC considers prompt medical management should be instituted if the patient presents persistent moderate diarrhoea with nausea and/or vomiting. The PRAC concluded that the product information of products containing tucatinib 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 tucatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tucatinib 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.