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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): cabozantinib

Procedure No. EMEA/H/C/PSUSA/00010180/202111

Period covered by the PSUR: 28 November 2018 – 28 November 2021

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Scientific conclusions

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

In view of the available data on cutaneous vasculitis from two reported cases with a positive rechallenge and a possible class effect, the PRAC concluded that the product information of medicinal products containing cabozantinib (Cabometyx and Cometriq) should be amended accordingly.

In view of the available data on pneumothorax namely an imbalance within clinical trial and a reported literature case for which a positive rechallenge was reported, and considering that a causal association between cabozantinib and pneumothorax is at least a possible probability, the PRAC concluded that the product information of medicinal products containing cabozantinib (Cabometyx and Cometriq) 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 cabozantinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cabozantinib 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.