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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/00010180/201811

Period covered by the PSUR: 29 November 2017 To: 28 November 2018

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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:

A search in Eudravigilance was performed for cabozantinib and the preferred term 'pain in extremity'. A total of 29 cases were reported with PT 'pain in extremity' and suspected drug 'Cometriq'. Time to onset is indicative of a causal association and varied between 1 day and 9 days. Furthermore, 'pain in extremity' is a known adverse drug reaction for Cabometyx (cabozantinib). Therefore, section 4.8 of the Summary of Products Characteristics should be updated to include "Pain in extremity" with a very common frequency, in line with the Product Information for Cabometyx. Furthermore, the Package Leaflet should be updated accordingly, to include "pain in the arms, hands, legs or feet'.

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 Cometriq 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.