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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/00010180/201711

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for cabozantinib, the scientific conclusions of CHMP are as follows:

A review of thromboembolic events showed that cerebrovascular accident, myocardial infarction and venous and arterial thrombosis occur following cabozantinib use in clinical trial and/or post-marketing setting. Although information on cases is limited or confounding factors are present in some cases, a causal relationship cannot be excluded. In addition, the literature indicates an increased risk of (arterial) thromboembolic events with VEGFR-TKIs. Therefore, it is recommended to update the product information with these events.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for cabozantinib the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing cabozantinib is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisations should be varied.