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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): nintedanib (respiratory indication)

Procedure No. EMEA/H/C/PSUSA/00010319/202010

Period covered by the PSUR: 15 April 2020 to 15 October 2020

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Scientific conclusions

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

In view of available data on thrombotic microangiopathy from the literature, spontaneous reports, and in view of a plausible mechanism of action and potential class effect, the PRAC considers a causal relationship between nintedanib and thrombotic microangiopathy could not be excluded.
The PRAC concluded that the product information of products containing nintedanib 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 nintedanib (respiratory indication) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nintedanib (respiratory indication) 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.