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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 (oncology indications)

Procedure No. EMEA/H/C/PSUSA/00010318/202210

Period covered by the PSUR: 15 October 2019 To: 15 October 2022

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on ischaemic colitis from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between nintedanib (oncology indications) and ischaemic colitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing nintedanib (oncology indications) 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 (oncology indications) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nintedanib (oncology indications) 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.