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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/00010319/201810

Period covered by the PSUR: 15/10/2017 To: 15/10/2018

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

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Annex IV

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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:

A search of MAH's databases using the PTs belonging to Medical Dictionary for Regulatory Reporting (MedDRA) HLT 'Colitis (excluding infective)' identified high number of cases reported in clinical trials and in post-marketing setting. Based on the substantial number of cases reporting colitis, the described cases of positive rechallenge and dechallenge, and the potential mechanism of action, the PRAC Rapporteur concluded that 'colitis' should be added as new adverse drug reaction with a frequency 'uncommon' respectively in section 4.8 of the SmPC.

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

Grounds for the variation to the terms of the marketing authorisation

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.