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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: nintedanib

Procedure No. EMEA/H/C/PSUSA/00010319/201504

Period covered by the PSUR: 15 Oct 2014 to 15 Apr 2015

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Scientific conclusions

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

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

Medicines that block vascular endothelial growth factor receptor (VEGFR) such as nintedanib might be associated with an increased risk of bleeding. In the 2 main studies with nintedanib, more patients treated with nintedanib than with placebo had bleeding events (10.3 % versus 7.8%).

In the postmarketing period a total of 91 individual case safety reports of haemorrhage (74 from the patient support programme and 17 from spontaneous sources) were reported with nintedanib. Twenty-nine (29) cases (31.9%) were serious, 62 (68.1%) were non-serious. One case (1.1%) was fatal. Of the 29 serious cases reporting a haemorrhagic event, epistaxis was the most common event. Of the 91 reported cases 29 patients were on concomitant anticoagulant or antithrombotic therapy (11 serious cases and 18 non serious), 14 patients were on concomitant therapy that could cause bleeding and 48 cases contained no data on this type of therapy. There was also one case with positive re-challenge with no concomitant drugs reported.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing nintedanib (respiratory indication) were warranted.

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 the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nintedanib is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.