EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2015
EMA/712740/2015
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: pazopanib

Procedure No. EMEA/H/C/PSUSA/00002321/201410

Period covered by the PSUR: 19.10.13 - 18.10.14

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Scientific conclusions

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

Pazopanib has been shown to be embryotoxic and teratogenic in preclinical studies. According to the harmacokinetic data in humans, pazopanib is eliminated slowly with a mean half-life (T1/2) of 30.9 hours after administration. Therefore, due to the relative high mean half-life, the PRAC considered necessary that patients used adequate contraception during the treatment and at least 2 weeks after-treatment. The SmPC and package leaflet have been updated accordingly.

Therefore, in view of available data regarding pazopanib, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for pazopanib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pazopanib 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.