17 September 2020
EMA/37441/2021
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): nilotinib

Procedure No. EMEA/H/C/PSUSA/00002162/202001

Period covered by the PSUR: 1 February 2019 – 31 January 2020

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 nilotinib, the scientific conclusions of CHMP are as follows:

In view of available data from spontaneous reports on rhabdomyolysis, a plausible temporal relationship and a plausible mechanism of action by comedication with statins, the PRAC considers a causal relationship between nilotinib and rhabdomyolysis caused by a drug-drug interaction with statins is at least a reasonable possibility. The PRAC concluded that the product information of products containing nilotinib should be amended accordingly.

In view of available data on the adverse reactions cardiac failure, pneumonia, and renal failure from a non-interventional study, the PRAC considers amendment of the frequencies in the product information of nilotinib warranted.

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 nilotinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nilotinib 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.