24 February 2022
EMA/253595/2022
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): neratinib

Procedure No. EMEA/H/C/PSUSA/00010712/202107

Period covered by the PSUR: 16 July 2020 to 16 July 2021

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 neratinib, the scientific conclusions of CHMP are as follows:

In view of available data on an increased risk of syncope from clinical trials and spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between neratinib and syncope is at least a reasonable possibility. The PRAC concluded that the product information of products containing neratinib 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 neratinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing neratinib 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.