11 November 2021
EMA/49355/2022
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): vandetanib

Procedure No. EMEA/H/C/PSUSA/00009327/202104

Period covered by the PSUR: 6 April 2020 – 6 April 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 vandetanib, the scientific conclusions of CHMP are as follows:

In view of available data regarding vandetanib including non-clinical data suggesting that vandetanib slows wound healing in an animal model and clinical data, mainly 23 cases in connection with an abnormal healing including 5 cases occurring in patients with surgical wounds and in light of a potential mechanism of action for drugs inhibiting VEGF pathway and a potential class effect, the PRAC concluded that the product information for vandetanib should be updated to reflect the risk of wound healing complications.

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