22 April 2021
EMA/346994/2021
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): rivaroxaban

Procedure No. EMEA/H/C/PSUSA/00002653/202009

Period covered by the PSUR: 15 September 2019 to 15 September 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 rivaroxaban, the scientific conclusions of CHMP are as follows:

In view of the available cumulative evaluation of overdose information that was performed during this report interval, new information on the highest ingested rivaroxaban dosages that have been reported, and as the risk of bleeding related to overdose is warranting clinical surveillance (which has been incorporated in the CCDS overdose section), the PRAC considers that such information is of value for prescribers. The PRAC concluded that the product information of products containing rivaroxaban 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 rivaroxaban the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rivaroxaban 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.