EMA/500342/2021
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): ticagrelor

Procedure No. EMEA/H/C/PSUSA/00002948/202012

Period covered by the PSUR: 01/01/2018 to 31/12/2020

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ticagrelor, the scientific conclusions of CHMP are as follows:

During PSUSA of ezetimibe / rosuvastatin (procedure PSUSA/00010271/202007) the PRAC considered that the ticagrelor and rosuvastatin interaction for which an extrapolation is proposed would also be relevant to be included in products containing ticagrelor as all the reported cases presented positive dechallenge for ticagrelor and provided a plausible mechanism of action. In addition, no warning regarding renal injury or potential mechanisms for interaction with rosuvastatin is included in the present product information of ticagrelor. During the PSUSA procedure of ezetimibe / rosuvastatin, the interaction causing rhabdomyolysis has been established between rosuvastatin and ticagrelor. The PRAC assessed the additional information submitted during the present PSUSA and concluded that the section 4.5 of the SmPC of products containing ticagrelor should be amended accordingly, to add the interaction with rosuvastatin.

The Package leaflet is updated 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 ticagrelor the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ticagrelor 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.