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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/00002653/201609

Period covered by the PSUR: 16/09/2015 - 15/09/2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for rivaroxaban, the scientific conclusions of CHMP are as follows:

Based on the data submitted in this PSUR regarding Stevens-Johnson syndrome (SJS), the PRAC concluded that Stevens-Johnson syndrome/Toxic Epidermal Necrolysis should be added as very rare adverse drug reactions. Patients appear to be at highest risk for these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first weeks of treatment. The PRAC also considered necessary to include a warning recommending to discontinue rivaroxaban at the first appearance of severe skin rash (e.g. spreading, intense and/or blistering), or any other sign of hypersensitivity in conjunction with mucosal lesions.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing rivaroxaban were 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 rivaroxaban the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing rivaroxaban is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.