EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): edoxaban

Procedure No. EMEA/H/C/PSUSA/00010387/201710

Period covered by the PSUR: 22 April 2017 – 21 October 2017

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Scientific conclusions

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

A number of cases of thrombocytopenia have been reported spontaneously and thrombocytopenia was uncommonly reported as an adverse event in pivotal clinical trials. Many of the spontaneously reported cases involved concomitant use of other medications and the causal role of edoxaban is difficult to establish, but equally in some cases the data are suggestive of a possible causal association. The MAH has already identified thrombocytopenia as a post-marketing adverse drug reaction (ADR) and the product information section 4.8 is being updated accordingly together with consequential changes to the Package Leaflet.

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