EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2017
EMA/373380/2017
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/00010387/201610

Period covered by the PSUR: 22 April 2016 to 21 October 2016

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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:

Cases of headache, abdominal pain, and dizziness have been reported and, whilst the detail of the cases as provided by the MAH is somewhat limited, for all 3 adverse drug reactions (ADRs) there is plausible temporal association and a proportion of positive de-challenge such that an association is possible. Confounding factors are not strongly supported by the data as presented and therefore do not influence the reflection of the above reported ADRs in the SmPC. On the basis of the data presented, abdominal pain, headache and dizziness are added to the list of adverse drug reactions (ADRs) of the SmPC and 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.