25 May 2023
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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/00010387/202210

Period covered by the PSUR: 22/10/2021 To: 21/10/2022

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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:

In view of available data on risk of drug drug interaction (DDI) between clarithromycin and edoxaban from the literature and spontaneous reports the PRAC considers clarithromycin significantly increases the exposure of edoxaban but the magnitude of the DDI is not expected to be clinically relevant however the statement related to the interaction between edoxaban and clarithromycin allows the prescriber to know that he can associate the two products without any dose adjustments. The PRAC concluded that the product information of products containing edoxaban should be amended accordingly.

In view of available data on anticoagulant-related nephropathy (ARN) from literature and the spontaneous reports some confirmed by renal biopsy, the PRAC considers a causal relationship between edoxaban and anticoagulant-related nephropathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing edoxaban 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 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.