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): enoxaparin

Procedure No. EMEA/H/C/PSUSA/00010833/202104

Period covered by the PSUR: 03/04/2020 to 03/04/2021

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Scientific conclusions

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

In view of available data on risk(s) from the literature and spontaneous reports, the PRAC considers a causal relationship between enoxaparin and acute generalized exanthematous pustulosis (AGEP) is at least a reasonable possibility, based on three cases with a probable causal relationship between enoxaparin and AGEP according to WHO criteria, and two of the three cases with a possible diagnosis of AGEP according to AGEP validation score of the EuroSCAR study group were identified. The PRAC concluded that the product information of products containing enoxaparin 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 enoxaparin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing enoxaparin 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.