25 April 2024
EMA/314979/2024
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): duloxetine

Procedure No. EMEA/H/C/PSUSA/00001187/202308

Period covered by the PSUR: 03 August 2020 to 03 August 2023

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Scientific conclusions

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

In view of available data on **neuroleptic malignant syndrome (NMS**) and **stress cardiomyopathy (Takotsubo cardiomyopathy)** from the literature, spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between duloxetine and NMS and stress cardiomyopathy (Takotsubo cardiomyopathy), is at least a reasonable possibility. The PRAC concluded that the product information of products containing duloxetine should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for duloxetine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing duloxetine 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.