30 March 2023
EMA/811281/2023
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): oxybutynin

Procedure No. EMEA/H/C/PSUSA/00002253/202207

Period covered by the PSUR: 17 July 2017 to: 17 July 2022

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Scientific conclusions

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

Oral formulation

In view of available data on risk of palpitations from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between Oxybutynin as per EURD list and Palpitation is at least a reasonable possibility. The PRAC concluded that the product information of oral formulations containing oxybutynin should be amended accordingly.

Transdermal formulation

In view of available data on medication errors concerning patients cutting the patches into smaller pieces, the PRAC considers that, in the current SmPC and PIL, it is not clear enough that the transdermal patches should not be cut or divided in any way. The PRAC concluded that the product information of the transdermal formulation containing oxybutynin 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 oxybutynin the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing oxybutynin 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.