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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): darifenacin

Procedure No. PSUSA/00000933/202410

Period covered by the PSUR: 3 years to 31 October 2024

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Scientific conclusions

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

In view of available data on risk(s) from the literature, spontaneous reports including in 8 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 darifenacin and confusional state is at least a reasonable possibility.

In view of available data on risk(s) from the literature, spontaneous reports including 2 cases with positive de-challenge, positive rechallenge and compatible TTO, 5 cases with a compatible TTO and positive de-challenge and other 13 cases with a close temporal association, the PRAC considers a causal relationship between darifenacin, and muscle spasm is at least a reasonable possibility.

The PRAC concluded that the product information of products containing darifenacin 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 darifenacin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing darifenacin 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.