EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 March 2022
EMA/567651/2022
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): desloratadine

Procedure No. EMEA/H/C/PSUSA/00000962/202107

Period covered by the PSUR: 16 July 2016 to 15 July 2021

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Scientific conclusions

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

In view of available data from the literature 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 desloratadine and depressed mood is at least a reasonable possibility. The PRAC concluded that the product information of products containing desloratadine should be amended accordingly.

As described in the literature and signal section of some MAHs, WHO identified a potential safety signal of dry eyes for desloratadine during the reporting period. Based on the anticholinergic properties of desloratadine and strengthened by the reports with a short time to onset and both de- and rechallenges described, the PRAC considers that "eye dryness" should be considered for inclusion in the product labels and patient leaflets.

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 desloratadine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing desloratadine 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.