EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 March 2022
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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): desloratadine / pseudoephedrine

Procedure No. EMEA/H/C/PSUSA/00000963/202107

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 / pseudoephedrine, 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 (PI) of products containing desloratadine / pseudoephedrine 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 desloratadine / pseudoephedrine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing desloratadine / pseudoephedrine 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.