EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/00000963/201607

Period covered by the PSUR: 16 July 2012 to 15 July 2016

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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:

Two literature reports identified a possible relationship between aggressive reaction/abnormal behaviour and desloratadine use with supportive temporal relationships, positive dechallenges and some with positive rechallenges. Similar cases were reported in Eudravigilance for the reference period. Considering the potential seriousness of these events in children, and the number of reported cases with positive dechallenge and rechallenge, the 'abnormal behaviour' and 'aggression' should be added to the list of adverse drug reactions (ADRs) of desloratadine.

A literature article published during the reference period describes 4 cases of epilepsy in children with a family history of epilepsy or relevant medical history. The causality was assessed as possible for each case, based on temporal association and positive dechallenge. Based on these new data, it could be concluded that desloratadine may aggravate pre-existing seizures in patients (and mainly in children) with medical history of seizures, and that caution should be recommended in treating epileptic patients or those susceptible to convulsions with desloratadine.

Based on 4 new publications regarding a possible association between desloratadine and QT prolongation were reported in the literature and the fact that 'QT prolongation' is already listed as an ADR of desloratadine-containing products, this adverse reaction should be listed as an ADR of any desloratadine-containing product.

Therefore, in view of the data presented in the reviewed PSURs, the PRAC considered that changes to the product information of medicinal products containing desloratadine were warranted.

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.