22 September 2011
EMA/CHMP/749646/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Desloratadine Teva

desloratadine

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Desloratadine Teva, 5mg film-coated tablets intended for intended for relief of symptoms associated with allergic rhinitis and urticaria. The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Desloratadine Teva is desloratadine, an "Other antihistamines for systemic use" (R06AX27). Desloratadine is an antihistamine. It works by blocking the receptors on which histamine, a substance in the body that causes allergic symptoms, normally fixes itself. When the receptors are blocked, histamine cannot have its effect, and this leads to a decrease in the symptoms of allergy.The approved indication is: "relief of symptoms associated with allergic rhinitis and urticaria".

Desloratadine Teva is a generic of Neoclarytin/ Aerius which has been authorised in the EU since 15 January 2001. Studies have demonstrated the satisfactory quality of Desloratadine Teva and its bioequivalence with the reference product Neoclarytin/ Aerius. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Desloratadine Teva will be implemented as part of the marketing authorisation.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Desloratadine Teva and therefore recommends the granting of the marketing authorisation.