17 November 2011
EMA/CHMP/796881/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Desloratadine Actavis

desloratadine

On 17 November 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 Actavis, 5mg film-coated tablets intended for relief of symptoms associated with allergic rhinitis and urticaria. The applicant for this medicinal product is Actavis Group PTC ehf. 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 Actavis is desloratadine, an antihistamine for systemic use (R06AX27). 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 Actavis is a generic of Aerius which has been authorised in the EU since 15 January 2001. Studies have demonstrated the satisfactory quality of Desloratadine Aerius and its bioequivalence with the reference product Aerius. A question and answer document on generic medicines can be found here.

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

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.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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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 Actavis and therefore recommends the granting of the marketing authorisation.