22 September 2011
EMA/CHMP/614223/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Desloratadine Krka

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 Krka 5 mg film-coated tablets intended for relief of symptoms associated with allergic rhinitis and urticaria. The applicant for this medicinal product is Krka,d.d., Novo mesto. 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 Krka is desloratadine, an "Other antihistamines for systemic use" (R06AX27). Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H1-receptors. The selectivity is achieved because the substance is excluded from the entry into the central nervous system.

Desloratadine Krka is a generic of Aerius which has been authorised in the EU since 15 January 2001. Studies have demonstrated the satisfactory quality of Desloratadine Krka 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 Krka will be implemented as part of the marketing authorisation.

The approved indication is: "relief of symptoms associated with allergic rhinitis and urticaria".

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 will be 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 Krka and therefore recommends the granting of the marketing authorisation.