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Questions and answers

Withdrawal of the marketing authorisation application for Desloratadine Krka (desloratadine)

On 14 October 2011, KrKa, d.d., Novo mesto officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Desloratadine Krka[1], for the relief of symptoms of allergic rhinitis or urticaria.

What is Desloratadine Krka?

Desloratadine Krka is a medicine containing the active substance desloratadine. It was to be available as tablets.

Desloratadine Krka was developed as a 'generic medicine'. This means that Desloratadine Krka was intended to be similar to a 'reference medicine' already authorised in the European Union called Aerius. For more information on generic medicines, see the question-and-answer document here.

What was Desloratadine Krka expected to be used for?

Desloratadine Krka was to be used to relieve the symptoms of allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) or urticaria (a skin condition caused by an allergy, with symptoms including itching and hives).

How is Desloratadine Krka expected to work?

The active substance in Desloratadine Krka, 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.

[1] The company submitted a revised notification letter dated 8 November 2011.

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What did the company present to support its application?

Because Desloratadine Krka was developed as a generic medicine, the company presented the results of studies carried out to investigate whether it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

How far into the evaluation was the application when it was withdrawn?

The evaluation had finished and the CHMP had given a positive opinion. The company withdrew before the European Commission had issued a decision on this opinion.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP lists of questions, at the time of the withdrawal, the CHMP had given a positive opinion, recommending that a marketing authorisation be granted for Desloratadine Krka for the relief of symptoms of allergic rhinitis or urticaria.

What were the reasons given by the company for withdrawing the application?

The letter from the company notifying the Agency of the withdrawal of the application is available under the tab 'All documents'.