European Medicines Agency

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QUESTIONS AND ANSWERS ON WITHDRAWAL OF AN APPLICATION FOR AN EXTENSION OF THE MARKETING AUTHORISATION for OPATANOL

International Non-proprietary Name (INN): **Olopatadine hydrochloride**

On 14 February 2006, Alcon Laboratories (U.K.) Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that they wish to withdraw their application for an extension of the marketing authorisation for Opatanol, to add a new pharmaceutical form, a nasal spray intended for a new use in the treatment of the signs and symptoms of seasonal and perennial rhinitis.

What is Opatanol nasal spray
Opatanol nasal spray is a solution containing 6 mg/ml of the active substance, olopatadine (as the hydrochloride).
Opatanol has been authorised in the European Union since 17 May 2002 as eye drops for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis.

What was Opatanol nasal spray expected to be used for?
Opatanol nasal spray was to be used to treat the signs and symptoms of allergic conditions of the nose, rhinitis (sneezing, itchy nose, runny nose and congestion), due to some materials (allergens) from pollens, house dust or animals.

How is Opatanol nasal spray expected to work?
Olopatadine, the active substance in Opatanol, is an antihistaminic. This means that it blocks the action of histamine, a natural substance in the body that is released when the body is exposed to an allergen. By blocking the action of histamine, Opatanol nasal spray was expected to help to control the signs and symptoms of allergic rhinitis.

What documentation was presented by the Company to support the application to the CHMP?
The effects of the medicine were first tested in experimental models before being studied in humans.
The Company submitted the results of clinical studies where Opatanol nasal spray used twice a day was compared to a placebo (a dummy treatment) in the treatment of allergic seasonal rhinitis (hay fever) and in perennial rhinitis. The studies in hay fever lasted two weeks and looked at how the symptoms were improved. The study in perennial rhinitis lasted one year.

How far into the evaluation was the application when it was withdrawn?
The application was at 'Day 120' when the Company withdrew. The CHMP had formulated a list of questions to be answered by the Company, and the Company had not yet responded to them.

The CHMP takes up to 210 days to evaluate an application for an extension of a marketing authorisation. Based on the review of the initial documentation, the CHMP prepares a list of questions (at day 120), which is sent to the Company. Once the Company has supplied responses to the questions, the CHMP reviews them and may, before giving an opinion, ask any remaining questions (at day 180) to be answered by the Company in writing or during a hearing. Following CHMP opinion, it usually takes around 2 months for the European Commission to update a licence.

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What was the recommendation of the CHMP at that time?
The CHMP had concerns and was of the provisional opinion that Opatanol nasal spray could not be approved, for the treatment of the signs and symptoms of seasonal and perennial rhinitis.

What were the main concerns of the CHMP?
The CHMP wanted to see the effect of Opatanol nasal spray compared to other medicines for the treatment of hay fever and perennial rhinitis.
In addition, the CHMP wanted to see the results of further tests carried out by the company to clarify the potential for harm of impurities contained in Opatanol nasal spray before making its recommendation.

What were the reasons given by the company for withdrawing the application?
The company's letter of withdrawal is published on the EMEA website and can be found here.

What are the consequences of the withdrawal for patients undergoing clinical trials / compassionate use programmes with Opatanol?
There are no ongoing clinical trials or compassionate use programmes with Opatanol nasal spray in the EU.

What is happening with regard to Opatanol eye drops used for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis?
Based on the currently available data, the CHMP has no concern regarding the use of Opatanol eye drops.