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EPAR summary for the public

Opatanol

olopatadine

This is a summary of the European public assessment report (EPAR) for Opatanol. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Opatanol.

What is Opatanol?

Opatanol is a clear eye drop solution, which contains the active substance olopatadine.

What is Opatanol used for?

Opatanol is used to treat the eye symptoms of seasonal allergic conjunctivitis (inflammation of the eyes caused by pollen in patients with hayfever). These include itching, redness and swelling.

The medicine can only be obtained with a prescription.

How is Opatanol used?

Opatanol is used in adults and children aged three years and older. It is given as one drop into the affected eye(s) twice a day, given eight hours apart. If another eye treatment is also being used, there should be a gap of five minutes between treatments; eye ointments should be administered last. Opatanol can be used for up to four months, if needed.

How does Opatanol work?

The active substance in Opatanol, olopatadine, is an antihistamine. Olopatadine works by blocking the receptors on which histamine, a substance in the body that causes allergic symptoms, normally attaches itself. When the receptors are blocked, histamine cannot have its effect, and this leads to a decrease in the symptoms of allergy.

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How has Opatanol been studied?

Opatanol has been studied in 688 patients in four main studies lasting between six and 14 weeks. Two of these studies included children. Opatanol was compared with cromolyn sodium (another anti-allergy medicine), with levocabastine (another antihistamine) and, in two studies, with placebo (a dummy treatment). In all of the studies, the main measure of effectiveness was based on the degree of itching and redness in the eye. One of the placebo studies also looked at these symptoms in relation to pollen counts.

What benefit has Opatanol shown during the studies?

Opatanol was as effective as cromolyn sodium and as levocabastine. When compared with placebo, Opatanol was more effective only when pollen counts were taken into account, showing that the higher the level of pollen in the air, the greater the difference between the effects of Opatanol and those of placebo. At lower pollen counts, there were no differences between the two treatments.

What is the risk associated with Opatanol?

The most common side effects with Opatanol (seen in between 1 and 10 patients in 100) are headache, dysgeusia (taste disturbances), eye pain, eye irritation, dry eyes, abnormal sensations in the eye, dry nose and fatigue (tiredness). For the full list of all side effects reported with Opatanol, see the Package Leaflet.

Opatanol contains benzalkonium chloride, which is known to discolour soft contact lenses. Therefore care should be taken by people who wear soft contact lenses.

Why has Opatanol been approved?

The CHMP decided that Opatanol's benefits are greater than its risks for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis and recommended that it be given marketing authorisation.

Other information about Opatanol

The European Commission granted a marketing authorisation valid throughout the European Union for Opatanol on 17 May 2002.

The full EPAR for Opatanol can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Opatanol, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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