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EPAR summary for the public

Emadine

emedastine

This is a summary of the European public assessment report (EPAR) for Emadine. 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 Emadine.

What is Emadine?

Emadine is a clear eye drop solution. It contains the active substance emedastine (0.5 mg/ml). Emadine is available in a bottle and in single-dose containers.

What is Emadine used for?

Emadine is used to treat the symptoms of seasonal allergic conjunctivitis (inflammation of the eyes caused by pollen in patients with hayfever). These symptoms include itching, redness and swelling. Emadine is used in adults and children aged three years and older.

The medicine can only be obtained with a prescription.

How is Emadine used?

Emadine is given as one drop in the affected eye(s) twice a day. Its effects have not been studied beyond six weeks. If more than one type of eye treatment is being used, each one should be given at least 10 minutes apart and any eye ointments should be given last.

Emadine is not recommended for patients older than 65 years or in patients who have problems with their liver or kidneys.

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How does Emadine work?

The active substance in Emadine, emedastine, is an antihistamine. It works by blocking the receptors that histamine normally attaches to. Histamine is a substance in the body that causes allergic symptoms. When the receptors are blocked, histamine cannot have its effect, which leads to a decrease in the symptoms of allergy.

How has Emadine been studied?

Emadine has been compared with levocabastine (another antihistamine) in one main study involving 222 patients with seasonal conjunctivitis aged four years and over. The main measure of effectiveness was the reduction in itching and redness, measured on a nine-point scale over up to six weeks.

The company also presented the results of studies in which patients received Emadine, levocabastine or placebo (a dummy treatment) before being subjected to an 'allergen challenge'. This is a test where patients with an allergy who are not currently showing any allergic symptoms receive a defined dose of an allergen (the substance that they are allergic to) to trigger an allergic reaction.

What benefit has Emadine shown during the studies?

Emadine was as effective as levocabastine in reducing symptoms of seasonal conjunctivitis. In both groups of patients, itching scores fell from around 5.1 at the start of the study, to around 3.8 after five minutes and around 2.7 after two hours. Similar reductions in redness scores were seen, falling from 4.5 to 3.7 after five minutes and 2.7 after two hours. In the long term, the itching scores fell from an average of around 3.9 on the first day, falling to 0.8 for Emadine and 2.0 for levocabastine after six weeks. For redness, the scores fell from around 2.7 to 0.5 for Emadine and to 1.1 for levocabastine. Similar results were seen in adults and in children.

The results of the allergen challenge tests supported these results.

What is the risk associated with Emadine?

The most common side effects with Emadine (which may affect between 1 and 2 patients in 100) are eye pain, eye pruritus (itchy eye) and conjunctival hyperaemia (increased blood flow to the eye, leading to redness).

The bottle form of Emadine contains benzalkonium chloride, which is known to discolour soft contact lenses. Therefore, care should be taken by people who wear soft contact lenses. For the full list of all side effects and restrictions with Emadine, see the package leaflet.

Why has Emadine been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Emadine's benefits are greater than its risks for the symptomatic treatment of seasonal allergic conjunctivitis. The Committee recommended that Emadine be given marketing authorisation.

Other information about Emadine

The European Commission granted a marketing authorisation valid throughout the European Union for Emadine on 27 January 1999.

The full EPAR for Emadine 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 Emadine, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2014.