EMA/628751/2014
EMEA/H/C/000310

EPAR summary for the public

Azomyr

desloratadine

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

What is Azomyr?

Azomyr is a medicine containing the active substance desloratadine. It is available as a 5 mg tablet, 2.5 mg and 5 mg orodispersible tablets (tablets that dissolve in the mouth), a 0.5 mg/ml syrup and a 0.5 mg/ml oral solution.

What is Azomyr used for?

Azomyr is 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).

The medicine can only be obtained with a prescription.

How is Azomyr used?

The recommended dose for adults and adolescents (12 years of age and over) is 5 mg once a day. The dose in children depends on their age. For children from one to five years of age, the dose is 1.25 mg once a day, taken as 2.5 ml syrup or oral solution. For children from six to 11 years of age, the dose is 2.5 mg once a day, taken either as 5 ml of the syrup or oral solution, or as one 2.5 mg orodispersible tablet. Adults and adolescents can use any form of the medicine.

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How does Azomyr work?

The active substance in Azomyr, desloratadine, is an antihistamine. It works by blocking the receptors to 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.

How has Azomyr been studied?

Azomyr has been studied in a total of eight studies involving about 4,800 adult and adolescent patients with allergic rhinitis (including four studies in seasonal allergic rhinitis, and two studies in patients who also had asthma). The effectiveness of Azomyr was measured by looking at the change in the symptoms (nasal discharge, itching, sneezing and congestion) before and after two or four weeks of treatment.

Azomyr has also been studied in 416 patients with urticaria. The effectiveness was measured by looking at the change in the symptoms (itching, number and size of hives, interference with sleep and daytime function) before and after six weeks of treatment.

In all studies, the effectiveness of Azomyr was compared with that of placebo (a dummy treatment).

Additional studies were presented to show that the syrup, oral solution and orodispersible tablets are treated by the body in the same way as the tablets, and to show that they can be used safely in children.

What benefit has Azomyr shown during the studies?

In allergic rhinitis, looking at the results of all studies taken together, two weeks of treatment with 5 mg Azomyr led to an average decrease in symptom score of 25 to 32%, compared with a decrease of 12 to 26% in the patients receiving placebo. In the two studies in urticaria, the decrease in symptom score after six weeks of treatment with Azomyr was 58 and 67%, compared with 40 and 33% in placebo-treated patients.

What is the risk associated with Azomyr?

In adults and adolescents, the most common side effects are fatigue (tiredness; 1.2%), dry mouth (0.8%) and headache (0.6%). The side effects seen in children are similar. In children less than two years of age, the most common side effects are diarrhoea (3.7%), fever (2.3%) and insomnia (difficulty sleeping; 2.3%). For the full list of all side effects reported with Azomyr, see the Package Leaflet.

Azomyr must not be used in people who are hypersensitive (allergic) to desloratadine, loratadine or any of the other ingredients.

Why has Azomyr been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Azomyr's benefits are greater than its risks for the relief of symptoms associated with allergic rhinitis or urticaria. The Committee recommended that Azomyr be given marketing authorisation.

Other information about Azomyr

The European Commission granted a marketing authorisation valid throughout the European Union for Azomyr on 15 January 2001.

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

This summary was last updated in 10-2014.