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EPAR summary for the public

Aerinaze

Desloratadine/pseudoephedrine

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

What is Aerinaze?

Aerinaze is a medicine containing the active substances desloratadine (2.5 mg) and pseudoephedrine (120 mg). It is available as blue and white modified-release tablets. 'Modified-release' means that the tablets have been made to allow one of the active substances to be released immediately and the other one released over a few hours.

What is Aerinaze used for?

Aerinaze is used to treat the symptoms of seasonal allergic rhinitis (hayfever, inflammation of the nasal passages caused by an allergy to pollen) in patients who have nasal congestion (a blocked nose).

The medicine can only be obtained with a prescription.

How is Aerinaze used?

In adults and adolescents over 12 years of age, the recommended dose of Aerinaze is one tablet twice a day, taken whole with a full glass of water. Treatment should continue for as short a time as possible and should stop when symptoms, chiefly the congestion (blocked nose), have disappeared. Treatment for more than 10 days is not advisable, as the medicine's effects on nasal congestion may wear off. Once the nose has cleared, patients can use desloratadine alone.

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How does Aerinaze work?

Aerinaze contains two active substances: desloratadine, an antihistamine, and pseudoephedrine, which is a nasal decongestant. Desloratadine 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. Pseudoephedrine works by stimulating nerve endings to release the chemical noradrenaline, which causes the blood vessels to constrict (narrow). This reduces the amount of fluid released from the vessels, resulting in less swelling and less mucus production in the nose. In Aerinaze, the two active substances are used together, since an antihistamine alone may not provide adequate relief for patients with nasal congestion.

Aerinaze tablets have two layers, one containing desloratadine, and the other containing pseudoephedrine. Desloratadine is released from its layer immediately after it is taken, while pseudoephedrine is released slowly over 12 hours. This means that patients only need to take the tablet twice a day.

Desloratadine has been available in the European Union (EU) since 2001, and pseudoephedrine is widely used in medicines that have been available over-the-counter for many years.

How has Aerinaze been studied?

The effectiveness of Aerinaze was assessed in two main studies involving a total of 1,248 adult and adolescent patients. In both studies, Aerinaze was compared with desloratadine alone and with pseudoephedrine alone. The main measures of effectiveness were the change in the severity of hayfever symptoms reported by the patients between before treatment started, and over the entire 15 days of treatment. The patients recorded their symptoms in a diary every 12 hours during the study, scoring on a standard symptom scale how severe the symptoms were over the previous 12-hour period.

What benefit has Aerinaze shown during the studies?

Aerinaze was more effective in reducing symptoms than either of the two active substances taken alone. When looking at all hayfever symptoms except for nasal congestion, patients taking Aerinaze reported a reduction in symptoms of 46.0%, compared with 35.9% in those taking pseudoephedrine alone. When looking at nasal congestion, patients taking Aerinaze had a reduction in symptoms of 37.4%, compared with 26.7% in those taking desloratadine alone. Similar results were seen in the second study.

What is the risk associated with Aerinaze?

The most common side effects with Aerinaze (seen in between 1 and 10 patients in 100) are tachycardia (fast heart rate), dry mouth, dizziness, psychomotor hyperactivity (restlessness), pharyngitis (sore throat), anorexia (loss of appetite), constipation, headache, fatigue (tiredness), insomnia (difficulty sleeping), somnolence (sleepiness), sleep disorders and nervousness. For the full list of all side effects reported with Aerinaze, see the Package Leaflet.

Aerinaze must not be used in people who are hypersensitive (allergic) to desloratadine, pseudoephedrine or any of the other ingredients, to adrenergic agents or to loratadine (another medicine used to treat allergies). It should not be used in people who are taking a monoamine oxidase inhibitor (such as some medicines used to treat depression) or who have stopped taking one of these medicines within the last two weeks. Aerinaze should also not be taken by people who have narrow-

angle glaucoma (increased pressure inside the eye), urinary retention (difficulty in passing urine), heart or blood vessel diseases including hypertension (high blood pressure), hyperthyroidism (an overactive thyroid gland), or a history or risk of haemorrhagic stroke (stroke caused by bleeding within the brain).

Why has Aerinaze been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Aerinaze's benefits are greater than its risks for the symptomatic treatment of seasonal allergic rhinitis when accompanied by nasal congestion and recommended that Aerinaze be given marketing authorisation.

Other information about Aerinaze

The European Commission granted a marketing authorisation valid throughout the European Union for Aerinaze on 30 July 2007.

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

This summary was last updated in 10-2011.