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EPAR summary for the public

Desloratadine Actavis

desloratadine

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

What is Desloratadine Actavis?

Desloratadine Actavis is a medicine containing the active substance desloratadine. It is available as tablets (5 mg).

Desloratadine Actavis is a 'generic medicine'. This means that Desloratadine Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Aerius. For more information on generic medicines, see the question-and-answer document here.

What is Desloratadine Actavis used for?

Desloratadine Actavis 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 Desloratadine Actavis used?

The recommended dose for adults and adolescents (12 years of age and over) is 5 mg once a day.

How does Desloratadine Actavis work?

The active substance in Desloratadine Actavis, desloratadine, is an antihistamine. It works by blocking the receptors to which histamine, a substance in the body that causes allergic symptoms, normally

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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 Desloratadine Actavis been studied?

Because Desloratadine Actavis is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Aerius. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Desloratadine Actavis?

Because Desloratadine Actavis is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Desloratadine Actavis been approved?

The CHMP concluded that, in accordance with EU requirements, Desloratadine Actavis has been shown to have comparable quality and to be bioequivalent to Aerius. Therefore, the CHMP's view was that, as for Aerius, the benefit outweighs the identified risk. The Committee recommended that Desloratadine Actavis be given marketing authorisation.

Other information about Desloratadine Actavis

The European Commission granted a marketing authorisation valid throughout the European Union for Desloratadine Actavis on 13 January 2012.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 12-2011.