EMEA/H/C/002419

EPAR summary for the public

Desloratadine Teva

desloratadine

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

What is Desloratadine Teva?

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

Desloratadine Teva is a 'generic medicine'. This means that Desloratadine Teva 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 Teva used for?

Desloratadine Teva 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 Teva used?

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How does Desloratadine Teva work?

The active substance in Desloratadine Teva, desloratadine, is an antihistamine. It works by blocking the receptors on which histamine, a substance in the body that causes allergic symptoms, normally fixes 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 Teva been studied?

Because Desloratadine Teva 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 Teva?

Because Desloratadine Teva 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 Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Desloratadine Teva 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 Teva be given marketing authorisation.

Other information about Desloratadine Teva

The European Commission granted a marketing authorisation valid throughout the European Union for Desloratadine Teva on 24 November 2011.

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

This summary was last updated in 10-2011.