



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/828337/2011
EMA/H/C/002310

EPAR summary for the public

Dasselta

desloratadine

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

What is Dasselta?

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

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

Dasselta 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 Dasselta used?

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



How does Dasselta work?

The active substance in Dasselta, 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 Dasselta been studied?

Because Dasselta 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 Dasselta?

Because Dasselta 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 Dasselta been approved?

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

Other information about Dasselta

The European Commission granted a marketing authorisation valid throughout the European Union for Dasselta on 28 November 2011.

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

This summary was last updated in 10-2011.