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Desloratadine ratiopharm (*desloratadine*)

An overview of Desloratadine ratiopharm and why it is authorised in the EU

What is Desloratadine ratiopharm and what it is used for?

Desloratadine ratiopharm is a medicine used in adults to relieve the symptoms of the following conditions:

- allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example hay fever or allergy to dust mites).
- chronic idiopathic urticaria (a recurrent skin condition with symptoms including itching and hives) as diagnosed by a doctor. 'Idiopathic' means that the cause of the disease is unknown.

Desloratadine ratiopharm contains the active substance desloratadine and is a 'generic medicine'. This means that Desloratadine ratiopharm contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Aerius. For more information on generic medicines, see the question-and-answer document here.

How is Desloratadine ratiopharm used?

Desloratadine ratiopharm can be obtained without a prescription. The medicine is available as tablets.

The recommended dose is one tablet once a day. The duration of treatment depends on the condition being treated.

If symptoms persist for more than 7 days or worsen, patients should seek medical advice. For more information about using Desloratadine ratiopharm, see the package leaflet or contact your doctor or pharmacist.

How does Desloratadine ratiopharm work?

The active substance in Desloratadine ratiopharm, 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.

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How has Desloratadine ratiopharm been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Aerius, and do not need to be repeated for Desloratadine ratiopharm.

As for every medicine, the company provided studies on the quality of Desloratadine ratiopharm. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Desloratadine ratiopharm?

Because Desloratadine ratiopharm 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 is Desloratadine ratiopharm authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Desloratadine ratiopharm has been shown to have comparable quality and to be bioequivalent to Aerius. Therefore, the Agency's view was that, as for Aerius, the benefits of Desloratadine ratiopharm outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Desloratadine ratiopharm?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Desloratadine ratiopharm have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Desloratadine ratiopharm are continuously monitored. Side effects reported with Desloratadine ratiopharm are carefully evaluated and any necessary action taken to protect patients.

Other information about Desloratadine ratiopharm

Desloratadine ratiopharm received a marketing authorisation valid throughout the EU on 13 January 2012.

Further information on Desloratadine ratiopharm can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/desloratadine-ratiopharm.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 01-2021.