

Package leaflet: Information for the user

Desloratadin Orion 5 mg orodispersible tablets

desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

For Rx:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

For OTC; to be completed nationally:

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Desloratadin Orion is and what it is used for
2. What you need to know before you take Desloratadin Orion
3. How to take Desloratadin Orion
4. Possible side effects
5. How to store Desloratadin Orion
6. Contents of the pack and other information

1. What Desloratadin Orion is and what it is used for

What Desloratadin Orion is

Desloratadin Orion contains desloratadine which is an antihistamine.

How Desloratadin Orion works

Desloratadin Orion is an antiallergy medicine. It helps control your allergic reaction and its symptoms.

When Desloratadin Orion should be used

For Rx:

Desloratadin Orion relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults and adolescents 12 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Desloratadin Orion is also used to relieve the symptoms associated with urticaria (a skin condition). These symptoms include itching and hives.

For OTC; to be completed nationally:

Desloratadin Orion relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults and adolescents 12 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Desloratadin Orion is also used in adults to relieve the symptoms associated with chronic idiopathic urticaria (a skin condition with unknown cause), initially diagnosed by a doctor. These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

For OTC; to be completed nationally:

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. What you need to know before you take Desloratadin Orion

Do not take Desloratadin Orion

- if you are allergic to desloratadine, or any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Desloratadin Orion:

- if you have poor kidney function
- if you have medical or familial history of seizures.

For OTC; to be completed nationally:

If you suffer from chronic idiopathic urticaria, this should be diagnosed by your doctor before taking Desloratadin Orion.

Children and adolescents

Do not give this medicine to children less than 12 years of age.

Other medicines and Desloratadin Orion

There are no known interactions of Desloratadin Orion with other medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Desloratadin Orion with food, drink and alcohol

Use caution when taking Desloratadin Orion with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Taking Desloratadin Orion is not recommended if you are pregnant or nursing a baby.

Driving and using machines

At the recommended dose, this medicine is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicine.

Desloratadin Orion orodispersible tablets contain aspartame

This medicine contains 3 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Other excipients

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially “sodium-free”.

3. How to take Desloratadin Orion

For Rx:

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in adults and adolescents 12 years of age and over

The recommended dose is one tablet once a day.

For OTC; to be completed nationally:

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use for allergic rhinitis

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

Use for chronic idiopathic urticaria

The recommended dose for adults is one tablet once a day.

If you need to use this medicine for longer than 3 months, please contact a doctor to check if your symptoms have another cause.

Place the tablet in your mouth and it will disperse rapidly before swallowing. Water or other liquid is not needed to swallow the dose.

For Rx:

Regarding the duration of treatment, your doctor determines the cause for treatment and then tells you how long you should take Desloratadin Orion. You should follow the instructions of your doctor.

For OTC; to be completed nationally:

The duration of treatment depends on the type, duration and course of your complaints. You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

Seek medical care immediately if you notice difficulties in breathing or swelling of lips, tongue or throat.

If you take more Desloratadin Orion than you should

For Rx:

Take Desloratadin Orion only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Desloratadin Orion than you were told to, tell your doctor or pharmacist immediately.

For OTC; to be completed nationally:

Take Desloratadin Orion only as described in this leaflet or as your doctor or pharmacist has told you. No serious problems are expected with accidental overdose. However, if you take more Desloratadin Orion than you should, tell your doctor or pharmacist immediately.

If you forget to take Desloratadin Orion

If you forget to take your dose on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and seek urgent medical advice straight away if you notice any of the following serious side effects:

Very rare (may affect up to 1 in 10 000 people):

- severe allergic reactions, including angioedema (difficulty in breathing, wheezing, itching, hives and/or swelling of the face, tongue or throat)

Other side effects that may occur

In clinical studies in adults, side effects were about the same as with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet. In adolescents, headache was the most commonly reported side effect.

Common (may affect up to 1 in 10 people):

- fatigue
- dry mouth
- headache.

Very rare (may affect up to 1 in 10 000 people):

- rash
- pounding or irregular heartbeat, fast heartbeat
- stomach ache, feeling sick (nausea), vomiting, upset stomach, diarrhoea
- dizziness, drowsiness, inability to sleep, seizures, restlessness with increased body movement
- muscle pain
- hallucinations
- liver inflammation, abnormal liver function tests.

Not known (frequency cannot be estimated from the available data):

- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- changes in the way the heart beats
- abnormal behaviour, aggression, depressed mood
- weight increased
- increased appetite
- dry eyes.

Additional side effects in children

Not known (frequency cannot be estimated from the available data):

- slow heartbeat, arrhythmia.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desloratadin Orion

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Desloratadin Orion contains

- The active substance is desloratadine. Each orodispersible tablet contains 5 mg desloratadine.
- The other ingredients are mannitol (E421), microcrystalline cellulose, croscarmellose sodium, maize starch, red iron oxide, polacrillin potassium, citric acid, peppermint flavour (maltodextrin, acacia, flavouring components), aspartame (E951), magnesium stearate.

What Desloratadin Orion looks like and contents of the pack

Light red, round flat faced, speckled tablets debossed with “D2” on one side and plain on the other. Diameter of approx. 8 mm.

Desloratadin Orion is available in blister packs containing 30, 90 and 100 orodispersible tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Orion Corporation Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

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