

Package leaflet: Information for the patient

Oradus 0.5 mg/ml oral solution

Desloratadine

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

- 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.

What is in this leaflet

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

1. What Oradus oral solution is and what it is used for

Oradus oral solution contains the active substance desloratadine which is an antihistamine. Oradus oral solution is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms. This medicine is used to relieve 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, adolescents, and children 1 year of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, red or watery eyes.

Oradus oral solution also relieves symptoms associated with urticaria (a skin condition caused by an allergy). 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.

2. What you need to know before you take Oradus oral solution

Do not take Oradus oral solution:

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

Warnings and precautions:

Talk to your doctor or pharmacist before taking Oradus oral solution:

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

Children and adolescents:

This medicine should not be used in children under 1 year of age.

Other medicines and Oradus:

There are no known interactions of Oradus oral solution with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Oradus oral solution with food, drink and alcohol:

This medicine can be taken with or without food. Use with caution when taking Oradus oral solution with alcohol.

Pregnancy, breast-feeding and fertility:

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are pregnant or breast-feeding a baby, taking this medicine is not recommended. There is no data available on male/female fertility.

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.

Oradus oral solution contains sorbitol:

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Oradus oral solution

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

Children:

Children 1 through 5 years of age:
The recommended dose is 2.5 ml (½ of a 5 ml spoonful) of oral solution once a day.

Children 6 through 11 years of age:

The recommended dose is 5 ml (one 5 ml spoonful) of oral solution once a day.

Adults and adolescents 12 years of age and older:

- The recommended dose is 10 ml (two 5 ml spoonful) of oral solution once a day.
- This medicine is for oral use. Swallow the dose of oral solution and then drink some water.
- Regarding the duration of treatment, your doctor will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Oradus oral solution.
- If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.

- If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your doctor may recommend you a longer term treatment.

- For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your doctor.

If you take more Oradus oral solution than you should

Take this medicine only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Oradus oral solution than you were told to, contact your doctor or pharmacist or go to the nearest hospital.

If you forget to take Oradus oral solution

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 stop taking Oradus oral solution

Do not stop taking this medicine unless advised by your doctor. 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. Cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away. The following common side effects (may affect up to 1 in 10 people) were reported: **Children** (less than 2 years of age): diarrhea, fever, insomnia.

Adults: fatigue, dry mouth, headache. The following side effects were reported very rarely in **adults:** (may affect up to 1 in 10,000 people) Severe allergic reactions, rash, pounding or irregular heartbeat, fast heartbeat, stomach ache, feeling sick (nausea), vomiting, upset stomach, diarrhea,

dizziness, drowsiness, inability to sleep, muscle pain, hallucinations, seizures, restlessness with increased body movement, liver inflammation, and abnormal liver function tests.

Other unknown side effects (frequency cannot be estimated from the available data) were reported in adults

- unusual weakness
 - change in the way the heart beats
 - 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
 - yellowing of the skin and/or eyes.
 - abnormal behavior.
 - aggression.
 - weight increased, increased appetite.
- Unknown Side effects (frequency cannot be estimated from the available data) were reported **in children:**
- slow heartbeat
 - change in the way the heart beats.
 - abnormal behavior.
 - aggression.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oradus oral solution

- 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 bottle and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine if you notice any change in the appearance of the oral solution.
- Do not throw away any medicines via wastewater. 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 Oradus oral solution contains:

- The active substance is desloratadine 0.5 mg / ml.
- The other ingredients are sorbitol, propylene glycol, sucralose, hypromellose, sodium citrate dihydrate, natural and artificial flavour (Tutti Frutti), citric acid, disodium edetate and purified water.

What Oradus oral solution looks like and contents of the pack

Oradus oral solution is available in a bottle of 150 ml as a clear colorless solution. A measuring spoon is provided, marked for doses of 2.5 ml and 5 ml.

Marketing Authorisation Holder and Manufacturer

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Reg. N°. Lebanon 166511/11

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists

This leaflet was last revised in May 2022.