



Package leaflet: Information for the patient

Oradus 5 mg film-coated tablets

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, consult to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What Oradus is and what it is used for

Oradus contains the active substance desloratadine. It is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms. This medicine relieves symptoms associated with the inflammation of the nasal passages caused by an allergy (allergic rhinitis) for example, hay fever or allergy to dust mites. These symptoms include sneezing, runny or itchy nose, itchy palate and itchy, red or watery eyes. This medicine is also used to relieve the 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 resume your normal daily activities and sleep.

This medicine is indicated for adults and adolescents (12 years of age and older).

2. What you need to know before you take Oradus

Do not take Oradus:

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

Warnings and precautions:

Consult to your doctor or pharmacist before taking Oradus:
- if you have poor kidney function.

Children and adolescents:

This medicine should not be used in children under 12 years old.

Other medicines and Oradus:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

There are no known interactions of this medicine with other medicines.



Oradus with food and drinks:

This medicine can be taken with or without food.

Pregnancy and breast-feeding:

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

If you are pregnant or breast-feeding, taking this medicine is not recommended.

Driving and using machines:

At the recommended dose, this medicine is not expected to cause you to be drowsy or less alert.

However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

3. How to take Oradus

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

Adults and adolescents (12 years of age and older):

- Take one tablet once a day.
- Swallow the tablet whole with water, with or without food.
- Regarding the duration of treatment, your doctor will determine the type of allergic disease you are suffering from and will determine for how long you should take this medicine.
- 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 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 of this medicine than you were told to, contact your doctor or pharmacist.

If you forget to take Oradus

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

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.

Seek immediate medical care if this occurs.

In adults, side effects were about the same as with a dummy tablet (placebo). However, fatigue, dry mouth and headache were reported more often than with a placebo.

In adolescents, headache was the most commonly reported side effect.

Very rare side effects have been reported:

Rash, palpitations, rapid heartbeat, stomach pain, nausea (feeling sick), 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Oradus

- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Store below 30°C. Keep away from light and humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- 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 contains

- The active substance is desloratadine.
- Each coated tablet contains 5 mg of desloratadine.
- The other ingredients are microcrystalline cellulose, maize starch, dibasic calcium phosphate, talc, FD & C Blue #2 aluminium lake, FD & C Red # 40 aluminium lake, polyvinyl alcohol, titanium dioxide, xanthan gum and lecithin.

What Oradus looks like and contents of the pack

Blue, round, film-coated tablets.
Oradus is available in boxes containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

Pharmaline, sal – Lebanon
P.O. Box 90201 Jdeidet-El-Metn, Lebanon
Contact us: pharmaline@maliagroup.com

Reg. N° for Oradus: 167090/10

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.

Council of Arab Health Ministers
Union of Arab Pharmacists

The leaflet was last revised in September 2012.