Package leaflet: Information for the patient

Deslor 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Deslor is and what it is used for

What Deslor is
Deslor contains desloratadine which is an antihistamine.

How Deslor works
Deslor is an anti-allergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Deslor should be used
Deslor 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.

Deslor 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 to resume your normal daily activities and sleep.

2. What you need to know before you take Deslor

Do not take Deslor
- 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, pharmacist or nurse before taking Deslor:
- if you have medical or familial history of seizures
- if you have poor kidney function.

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

Other medicines and Deslor
There are no known interactions of Deslor with other medicines.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Deslor with food, drink and alcohol
Deslor may be taken with or without a meal.
Use caution when taking Deslor 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 Deslor is not recommended if you are pregnant or nursing a baby.

Fertility
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 medicinal product.

3. How to take Deslor

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

Adults and adolescents 12 years of age and over
The recommended dose is one tablet once a day with water, with or without food.

This medicine is for oral use.
Swallow the tablet whole.

Regarding the **duration of treatment**, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Deslor.

- If your **allergic rhinitis is intermittent** (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician 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 physician 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 physician.

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

If you forget to take Deslor
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 Deslor
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

During the marketing of desloratadine, 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**.

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.

In clinical studies with desloratadine, the following side effects were reported as:

Common: may affect up to 1 in 10 people
- Fatigue
- Dry mouth
- Headache.

<u>Adults</u>
During the marketing of desloratadine, the following side effects were reported as:

Very rare: 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
- Diarrhoea
- Dizziness
- Drowsiness
- Inability to sleep
- Muscle pain
- Hallucinations
- Seizures
- Restlessness with increased body movement
- Liver inflammation
- Abnormal liver function tests.

Not known: frequency cannot be estimated from the available data
- Abnormal behaviour
- Aggression
- Depressed mood
- Dry eyes
- 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
- Change in the way the heart beats
- Weight increased
- Increased appetite.

Children
Not known: frequency cannot be estimated from the available data
- Abnormal behaviour
- Aggression
- Slow heartbeat
- Change in the way the heart beats
- Weight increased
- Increased appetite.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Deslor

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice any change in the appearance of the tablets.

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 Deslor contains
- The active substance is desloratadine. Each film-coated tablet contains 5 mg desloratadine.
- The other ingredients are:
  Film-coated tablet core: Maize starch, Cellulose, microcrystalline, Hypromellose, Silica Colloidal anhydrous, Hydrogenated vegetable oil (Type 1).
  Film-coated tablet coating: Opadry Blue 03B50689 (Hypromellose E464, Titanium dioxide E171, Macrogol 400 E1521, Indigo Carmine Aluminum Lake E132)

What Deslor looks like and contents of the pack
Deslor is a light blue, round shaped, biconvex film coated tablets, with "5" debossed on one side. Diameter 6.50 ± 0.10 mm.

Deslor is supplied in blister pack comprising of OPA/ ALU/ PVC/ ALU and in blister pack comprising of PVC/ Aclar/ ALU).

Pack sizes (unit dose):
30 x 1 film coated tablets.

Not all pack sizes may be marketed.

Pack sizes (not unit dose):
30 film coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Lek Pharmaceuticals d.d., Trimlini 2 D, 9220 Lendava, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:
Denmark Deslor

Ireland Deslor 5 mg Film-Coated Tablets

This leaflet was last revised in 04/2022.