Package leaflet: Information for the patient

Deslor 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, 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 oral solution 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 oral solution 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, adolescents and children 1 year of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Deslor oral solution 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 to 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.

Use in children and adolescents
Do not give this medicine to children less than 1 year 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 oral solution 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.

Deslor contains sorbitol, propylene glycol and sodium
This medicine contains up to 97.5 mg sorbitol in each ml of oral solution. 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.

This medicine contains 102.30 mg propylene glycol in each ml of oral solution.

This medicinal product contains 3.85 mg sodium (main component of cooking/table salt) in each ml of oral solution. This is equivalent to 0.19% of the recommended maximum daily dietary intake of sodium for an adult.

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.

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 over
The recommended dose is 10 ml (two 5 ml spoonfuls) of oral solution once a day.

In case an oral measuring syringe is provided with the bottle of oral solution, you can alternatively use it to take the appropriate amount of oral solution.

This medicine is for oral use.

Swallow the dose of oral solution, and then drink some water. You can take this medicine with or without food.

How to measure the dose
A measuring spoon marked for doses of 2.5 ml and 5 ml or a 5 ml syringe marked at each 0.5 ml is provided with this medicine. To measure the medicine using the syringe:
- Remove the bottle cap and keep it safely
- Put the end of the syringe into the solution
- Pull the plunger to measure the dose you need
- Remove the syringe from the bottle and close the bottle.

If you see air bubbles in the oral syringe after drawing up the solution, turn the oral syringe in an upright position with the tip pointing up. The air will move to the top of the oral syringe. Pull the plunger back towards you and then push it back gently into the oral syringe to get rid of the bubbles. Do not worry about a few tiny bubbles.

Ask you doctor or pharmacist if you need advice on how to measure out the medicine.

Giving the medicine using the syringe:
- Make sure the child is supported in an upright position.
- Put the tip of the syringe carefully into the child's mouth. Point the tip of the syringe towards the inside of the cheek.
- Slowly push down the plunger of the syringe: Do not squirt it out quickly. The medicine will trickle into the child's mouth.
- Allow the child time to swallow the medicine.

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 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 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 oral solution only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Deslor oral solution 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 most children and adults, side effects with Deslor were about the same as with a dummy solution or tablet. However, common side effects in children less than 2 years of age were diarrhoea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

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

<u>Children</u>
Common in children less than 2 years of age: may affect up to 1 in 10 children
- Diarrhoea
- Fever
- Insomnia.

<u>Adults</u>
Common: may affect up to 1 in 10 people
- Fatigue
- Dry mouth
- Headache.

During the marketing of desloratadine, the following side effects were reported as:

Adults

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 for Ireland via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. For Malta, you can also report side effects via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. 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 bottle and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Shelf life after first opening of the bottles: 2 months

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 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 ml of oral solution contains 0.5 mg desloratadine.
- The other ingredients of the oral solution are sorbitol liquid non-crystallizing (E420), propylene glycol (E1520), citric acid monohydrate, sodium citrate (E331), hypromellose 2910, sucralose, disodium edetate, "tutti frutti" flavouring, purified water.

What Deslor looks like and contents of the pack
Clear, colourless solution.

The oral solution is packed in Type III amber glass bottles closed with a polypropylene child resistant (C/R) screw closure having a multi-ply polyethylene-faced liner and is inserted in a carton.

All packages are supplied with a measuring spoon CE 0373 marked for doses of 2.5 ml and 5 ml or an oral measuring syringe CE 0373 of a final volume of 5 ml marked on every 0.5 ml.

Pack sizes:
100 ml oral solution

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.
Balkanpharma Troyan AD, 1 Krayrechna Str., Troyan 5600, Bulgaria.

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

Denmark	Deslor
Ireland	Deslor 0.5 mg/ml oral solution
Malta	Deslor 0.5 mg/ml oral solution

This leaflet was last revised in 04/2022.