



## Package leaflet: Information for the user

### Deslin 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. See section 4.

#### What is in this leaflet:

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

#### 1. What Deslin is and what it is used for

Deslin contains Desloratadine which is an antihistamine. Deslin oral solution is an allergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

Deslin relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, 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.

Deslin 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.

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

#### 2. What you need to know before you take Deslin

##### Do not take Deslin:

- 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 Deslin

- if you have poor kidney function.

##### Use in children and adolescents

Do not give this medicine to children less than 1 year of age.

Deslin oral solution is indicated for children 1 through 11 years of age, adolescents (12 years of age and older), and adults, including the elderly.

##### Other medicines and Deslin

There are no known interactions of Deslin with other medicines.

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

##### Deslin with food and drink

Deslin may be taken with or without a meal.

##### Pregnancy, breast-feeding and fertility

###### Pregnancy

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 Deslin is not recommended if you are pregnant or nursing a baby.

###### Fertility

There are no fertility data available.

##### 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.

Deslin oral solution contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### 3. How to take Deslin

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 children

###### Children 1-5 years of age:

The recommended dose is 2.5 ml of oral solution once a day.

###### Children 6-11 years of age:

The recommended dose is 5 ml of oral solution once a day.

##### Adults and adolescents

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

The recommended dose is 10 ml 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.

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 Deslin.

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 doctor.

#### If you take more Deslin than you should

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

#### If you forget to take Deslin

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 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 like:

Headache, insomnia, QT prolongation, Dry mouth, Diarrhoea, Jaundice, Photosensitivity, Fatigue, Fever, Asthenia.

In most children and adults, side effects 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.

During the marketing of Desloratadine, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely.

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

Very rare, the following 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
- liver inflammation
- abnormal liver function tests.

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

#### To report any side effect(s):

##### • Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd.a.gov.sa
- Website: www.sfd.a.gov.sa/npc

##### • Other GCC States:

Please contact the relevant competent authority.

#### 5. How to store Deslin

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 on the bottle after EXP. The expiry date refers to the last day of that month.

Store in the original primary container.

Do not store above 30°C

Protect from light

After first opening, use within 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 Deslin contains

- The active substance is Desloratadine 0.5 mg/ml.
- The other ingredients are: sodium citrate, sorbitol, sucralose, citric acid anhydrous, propylene glycol, hypromellose, tutti-frutti flavor and purified water.

##### What Deslin looks like and contents of the pack

Deslin oral solution is available in bottles with a childproof cap. For all packages a measuring cup is provided or a measuring syringe.

150ml oral solution

##### Marketing Authorization Holder & Manufacturer:

AJA Pharmaceutical Industries Company, Ltd.  
Hail Industrial City MODON, Street No 32  
PO Box 6979, Hail 55414  
Kingdom of Saudi Arabia  
Tel: +966112687900

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#### This is a Medicament

- 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 the experts in medicines, their 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