

Desloratadine 0.5mg/ml Oral Solution

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 Desloratadine Oral Solution is and what it is used for**
- 2 What you need to know before you take Desloratadine Oral Solution**
- 3 How to take Desloratadine Oral Solution**
- 4 Possible side effects**
- 5 How to store Desloratadine Oral Solution**
- 6 Contents of the pack and other information**

1 What Desloratadine Oral Solution is and what it is used for

Desloratadine Oral Solution is an anti-allergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

Desloratadine 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.

Desloratadine 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 Desloratadine Oral Solution

Do not take Desloratadine Oral Solution

- 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 or pharmacist before taking Desloratadine Oral Solution:

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

Children and adolescents

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

Other medicines and Desloratadine Oral Solution

There are no known interactions of Desloratadine Oral Solution with other medicines.

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

Desloratadine Oral Solution with food, drink and alcohol

Desloratadine Oral Solution may be taken with or without a meal. Use caution when taking Desloratadine Oral Solution 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 Desloratadine Oral Solution is not recommended if you are pregnant or breast-feeding.

The effect of Desloratadine Oral Solution on fertility is not known.

Driving and using machines

At the recommended dose, Desloratadine Oral Solution 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. Do not 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.

Desloratadine Oral Solution contains sorbitol (E 420)

This medicine contains 1471.5mg of sorbitol (E 420) per 10ml adult dose. 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.

Desloratadine Oral Solution contains sodium

This medicine contains 38.54 mg sodium (main component of cooking/table salt) in each 10ml adult dose. This is equivalent to 1.93% of the recommended maximum daily dietary intake of sodium for an adult.

Desloratadine Oral Solution contains propylene glycol (E 1520)

This medicine contains 1023mg of propylene glycol per 10ml adult dose.

3 How to take Desloratadine Oral Solution

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

The recommended dose of Desloratadine Oral Solution is:

Children 1 through to 5 years of age: 2.5ml (as marked on spoon) of oral solution once a day.

Children 6 through to 11 years of age: 5ml (one 5ml spoonful) of oral solution once a day.

Adults and adolescents (12 years of age and older): 10ml (two 5ml 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.

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

Your doctor will determine the duration of treatment which will depend on the severity of the allergic condition and may be variable from patient to patient. Therefore you should follow the instructions of your doctor.

If you take more Desloratadine Oral Solution than you should

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

If you forget to take Desloratadine Oral Solution

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 stop taking Desloratadine Oral Solution

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.

During the marketing of Desloratadine Oral Solution, 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 Desloratadine Oral Solution 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 Oral Solution, the following side effects were reported as:

Children

Common in children less than 2 years of age (may affect up to 1 in 10 children):

- diarrhoea
- fever
- insomnia.

Adults

Common (may affect up to 1 in 10 people):

- fatigue
- dry mouth
- headache.

During the marketing of Desloratadine Oral Solution, 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):

- 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

- abnormal behaviour
- aggression
- change in the way the heart beats
- weight increased, increased appetite.

Children

Not known (frequency cannot be estimated from the available data):

- slow heartbeat
- change in the way the heart beats
- abnormal behaviour
- aggression.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 How to store Desloratadine Oral Solution

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Store in the original package. Do not freeze. After first opening use within 2 months.

Do not take 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 Desloratadine Oral Solution contains

The active substance is desloratadine. 1ml of oral solution contains 0.5mg desloratadine.

The other ingredients of the oral solution are:

Sorbitol, liquid (non-crystallizing), Propylene glycol, Citric acid monohydrate, Sodium citrate, Hypromellose 2910, Sucralose, Disodium edentate, Tutti frutti, Purified water.

What Desloratadine Oral Solution looks like and contents of the pack

Desloratadine Oral Solution is presented as a clear colourless solution, free from foreign matters.

Pack Size: 100ml.

Desloratadine 0.5mg/ml Oral Solution is supplied in amber glass bottles containing 100ml and closed with a plastic child resistant screw cap. Each bottle is supplied in a cardboard box with a measuring spoon marked for doses of 2.5ml and 5ml or an oral measuring syringe of a final volume of 5ml marked on every 0.5ml.

Marketing Authorisation Holder

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
Middlesex
HA1 4HF
United Kingdom

Manufacturer

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

This leaflet was last revised in May 2020.

If you would like a leaflet with larger text, please contact 01271 385257.