

# Desloratadine 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.**

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

**What Desloratadine Oral Solution is**  
Desloratadine Oral Solution contains desloratadine which is an antihistamine.

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

**When Desloratadine Oral Solution should be used**  
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, pharmacist or nurse 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 and breast-feeding**  
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 nursing a baby.

**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.

**Desloratadine Oral Solution contains sorbitol**  
This medicine contains 147.15 mg sorbitol in each ml, which is equivalent to 1471.5 mg per 10 ml. 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 propylene glycol**  
This medicine contains 102.30 mg propylene glycol in each ml, which is equivalent to 1023 mg per 10 ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

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.

**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.

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 Desloratadine 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 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 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 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, pharmacist or nurse **immediately**.

**If you forget to take Desloratadine Oral Solution**

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 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 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, the following side effects were reported as:

Children

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

- diarrhoea
- fever
- insomnia

Adults

Common: the following 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: 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
- 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
- change in the way the heart beats
- abnormal behaviour
- aggression

Children

The following other side effects were reported in children as:

Not known: frequency cannot be estimated from the available data

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

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**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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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.**

This medicinal product does not require any special temperature storage conditions. Keep bottle in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and bottle after ‘EXP’. The expiry date refers to the last day of that month.

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 Desloratadine Oral Solution contains**

- The active substance is desloratadine. Each ml Desloratadine Oral Solution contains 0.5 mg desloratadine.
- The other ingredients are: liquid sorbitol (E420) (non-crystallizing), propylene glycol, citric acid monohydrate, sodium citrate, hypromellose 2910, sucralose, disodium edetate, Tutti frutti flavouring, 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.

Desloratadine Oral Solution is supplied in Type III amber glass bottles closed with either a plastic child resistant (C/R) screw closure having a multiply polyethylene-faced liner, or a plastic child resistant (C/R) screw closure consisting of an outer and an inner layer of polypropylene and polyethylene respectively.

The bottles are subsequently packed into cardboard boxes.

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

*Pack sizes*

50 ml, 60 ml, 100 ml, 120 ml, 150 ml and 300 ml oral solution.

The 50 and 60 ml are both packaged in 60 ml bottles, the 100 ml are packaged in 100 ml or 115 ml volume of bottles, the 120 ml are packaged in 125 ml bottles and the 150 ml are packaged in 150 ml bottles and the 300 ml are packaged in 300 ml bottles.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Accord Healthcare Ireland Limited  
Euro House  
Euro Business Park  
Little Island  
Cork T45 K857  
Ireland

**Manufacturer**

Balkanpharma Troyan AD  
1 Krayrechna Str.  
Troyan 5600  
Bulgaria

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