

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALVOTADIN 0.5 mg/ml

ORAL SOLUTION

DESLORATADIN

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

What is in this leaflet?

1. What Alvotadin, oral solution is and what it is used for
2. Before you use Alvotadin, oral solution
3. How to take Alvotadin, oral solution?
4. Possible side effects
5. How to store Alvotadin, oral solution?
6. Further information

1. WHAT ALVOTADIN ORAL SOLUTION IS AND WHAT IT IS USED FOR

Alvotadin oral solution is the medication which treats allergies that does not cause drowsiness. It helps to control allergic response and associated symptoms.

Alvotadin oral solution relieves symptoms of allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever and allergies to dust mites) such as sneezing, itching and runny nose, itching of the palate and redness, itching and watery eyes.

Alvotadin oral solution is also used to relieve the symptoms associated with urticaria (skin changes due to allergies).

These symptoms include hives and itching of the skin. The symptoms are alleviated throughout the day, which helps you perform your normal daily activities and normal sleep.

2. BEFORE YOU USE ALVOTADIN, ORAL SOLUTION

Do not use Alvotadin, oral solution:

- If you are allergic (hypersensitive) to desloratadin, loratadin or any of the other ingredients of Alvotadin, oral solution.

Alvotadin oral solution is intended for use among children from 1 to 11 years old, among adolescents (aged 12 and older), even among the adults and elderly people.

Take special care with Alvotadin, oral solution

- If you have impaired kidney function

Before treatment with Alvotadin, oral solution, consult with your doctor if this applies to you, or if you are unsure.

Using other medicines

There are not any known interactions of Alvotadin oral solution with other drugs.

Using Alvotadin, oral solution with food and drink

Alvotadin can be used with meals or on an empty stomach.

Pregnancy and breast-feeding

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

It is not recommended to take Alvotadin oral solution during pregnancy and breastfeeding.

Driving and using machines

If taken in recommended dose, Alvotadin oral solution should not cause drowsiness or decrease alertness. However, though very rarely, some people can experience drowsiness, which can affect their ability to drive or use machines.

Important information about some of the ingredients of Alvotadin, oral solution

Alvotadin oral solution contains sorbitol. If a doctor told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Alvotadin oral solution contains propylene glycol, which may cause an alcohol-related symptoms. If you have additional questions, please consult your doctor.

3. HOW TO TAKE ALVOTADIN, ORAL SOLUTION?

Children aged 1 to 5 years: 2.5 ml (half a teaspoon of 5ml) of oral solution, once a day.

Children aged 6 to 11 years: 5ml (one teaspoon of 5ml) of oral solution, once a day.

Adults and adolescents (12 years and older): 10ml (2 teaspoons of 5ml) of oral solution, once a day.

In case that you receive the oral dosing syringe with the oral solution bottle, you can use it to measure the correct dose of oral solution.

Swallow the dose of oral solution, and then drink some water. This medicine can be taken after meals or on an empty stomach.

Your doctor will determine which type of allergic rhinitis you are suffering from and will decide accordingly how long you should take Alvotadin oral solution. If you suffer from intermittent allergic rhinitis (symptoms are present less than 4 days per week or less than 4 weeks), the doctor will make a recommendation on the duration of treatment after assessment of your medical history. If you suffer from persistent allergic rhinitis (symptoms are present 4 or more days a week and for more than 4 weeks), your doctor may prescribe a longer treatment.

Length of urticaria treatment varies from patient to patient, so follow the instructions of your doctor.

If you take more Alvotadin oral solution than you should

Take Alvotadin oral solution only in the manner that we have prescribed. Serious problems with accidental overdose should not occur. However, if you take more Alvotadin oral solution than you were prescribed, consult your doctor or pharmacist.

If you forget to take Alvotadin, oral solution

If you forget to take a dose, take it as soon as possible, and then continue to take your medication on normal schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Alvotadin oral solution

We recommend you to follow the treatment regimen and, if necessary, consult your doctor about discontinuation of treatment.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Alvotadin oral solution can cause side effects, although not everybody gets them.

In most children and adults, side effects were the same as in the use of a placebo. However, common side effects in children younger than 2 years were diarrhea, fever and insomnia, while in adults, fatigue, dry mouth and headache were recorded more frequently than after taking a placebo.

After placing desloratadine on the market the cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives, swelling), and rash were recorded very rarely. The cases of palpitations (heart beat sensation), increased heart rate, abdominal pain, nausea, vomiting, irritated stomach, diarrhea, dizziness, drowsiness, insomnia, muscle pain, hallucinations, seizures, restlessness with increased body movement, liver inflammation and abnormal values of liver function test parameters, were also rarely recorded.

If any of the above mentioned side effects increases or you notice any other side effect which is not listed in this information leaflet, you must notify your doctor or pharmacist.

5. HOW TO STORE ALVOTADIN, ORAL SOLUTION

Keep out of the reach and sight of children.

Unused medication must be destroyed according to current regulations.

Do not use Alvotadin oral solution after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Expiry date: 2 years.

Do not store above 30 °C. Store in the original carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION***What Alvotadin, oral solution contains***

- The active substance is desloratadin, 0.5 mg/ml.
- The other ingredients are:
 - Hypromellose 2910;
 - Sucralose;
 - Citric acid; anhydrous;
 - Sodium-citrate;
 - Sorbitol, liquid, non-crystallizing;
 - Propylene glycol;
 - Tutti-frutti aroma, liquid;
 - Purified water.

What Alvotadin, oral solution looks like and contents of the pack

The clear, colorless solution

Alvotadin oral solution comes in bottles of brown glass type III with white safety closure that children cannot open.

The bottle is packed in a cardboard box with a plastic spoon for dosing. Alvotadin oral solution 0.5 mg/ml is available as the volume of 60 ml and 150 ml.

The regime of dispensing

The drug is issued on prescription.

Manufacturer

Alvogen Ltd. Barice

Pasnjacka bb, Barice, Municipality of Plandiste, Serbia