

## **PACKAGE LEAFLET: Information for the patient**

### **ALERGO**

Oral solution – 0.5 mg / ml

(Desloratadine)

#### **Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication 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 AlerGO is and what it is used for
2. What you need to know before you take AlerGO
3. How to take AlerGO
4. Possible side effects
5. How to store AlerGO
6. Other information

#### **1. WHAT ALERGO IS AND WHAT IT IS USED FOR**

AlerGO oral solution contains the active substance desloratadine which is an antihistamine.

AlerGO is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

AlerGO 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.

AlerGO 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 ALERGO**

### **Do not take AlerGO if:**

- you are allergic to desloratadine or to any of the other ingredients of this medicine (listed in section 6) or to loratadine.

### **Warning and precautions**

Talk to your doctor or pharmacist before taking AlerGO:

- 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 AlerGO**

There are no known interactions of AlerGO with other medicines.

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

### **AlerGO oral solution with food, drink and alcohol**

AlerGO may be taken with or without a meal.

Use caution when taking desloratadine with alcohol.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

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.

### **Important information about some of the excipients of AlerGO oral solution**

#### AlerGO oral solution contains 280 mg sorbitol (E420) in 1 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 this medicine.

#### AlerGO oral solution contains 10 mg propylene glycol (E1520) in 1 ml of oral solution.

#### AlerGO oral solution contains sodium

This medicine contains 48.9 mg sodium per 10 ml oral solution, equivalent to 2.4% of the recommended maximum daily intake of 2 g sodium for an adult.

#### AlerGO oral solution contains sodium benzoate (E 211)

This medicine contains 1 mg sodium benzoate in 1 ml of oral solution, which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

### **3. HOW TO TAKE ALERGO**

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

A dosing cup and a dosing syringe are provided with the bottle of oral solution. You can use either of them to take the appropriate amount of oral solution according to the dosage described below.

#### **Use in children**

Children 1 through 5 years of age:

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

Children 6 through 11 years of age:

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

#### **Use in adults and adolescents 12 years of age and over**

The recommended dose is 10 ml of oral solution once a day.

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 AlerGO 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 AlerGO than you should**

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

**If you forget to take AlerGO**

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 AlerGO**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, AlerGO 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 AlerGO were about the same as with a dummy (placebo) 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:

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

- fatigue
- dry mouth
- headache

## **Children**

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

- diarrhoea
- fever
- insomnia

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

**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
- change in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite
- depressed mood
- dry eyes

### **Children**

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

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

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

### **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 to the Pharmacovigilance Department of the National Agency of Drugs and Medical Devices at the email address [farmakovigjilenca@akbpm.gov.al](mailto:farmakovigjilenca@akbpm.gov.al) or via the website [www.akbpm.gov.al/formulari-raportimi](http://www.akbpm.gov.al/formulari-raportimi). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE ALERGO**

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.

Do not freeze.

Store in the original package away from light. Do not store above 25°C.

Do not use this medicine if you notice any change in the appearance of the oral solution.

## **6. OTHER INFORMATION**

### **What AlerGO 0.5 mg / ml oral solution contains**

The **active substance** is desloratadine.

1 ml oral solution contains 0.5 mg desloratadine.

The **excipients** are: propylene glycol, hypromellose, sorbitol, sucralose, sodium benzoate, citric acid monohydrate, sodium citrate, disodium EDTA, strawberry essence, caramel essence and purified water.

### **Contents of the pack**

Carton box with 1 bottle of 150 ml oral solution accompanied by a dosing cup and a dosing syringe.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

**This leaflet was formulated in September 2024.**