

PATIENT INFORMATION LEAFLET

ALORES 2.5 mg/5 ml syrup

For oral use only.

- **Active substances:** Each 5 ml syrup (1 spoon) contains 2.5 mg desloratadine.
- **Excipients:** Propylene glycol, sorbitol 70% (E420), citric acid monohydrate, sodium citrate, sodium benzoate (E211), sodium edetate, sucrose, strawberry flavor, FDC yellow no.6 (E110), sodium hydroxide and deionized water.

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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

- 1. What ALORES is and what it is used for?**
- 2. What you need to know before you take ALORES**
- 3. How to take ALORES?**
- 4. Possible side effects**
- 5. How to store ALORES?**

1. What ALORES is and what it is used for?

- ALORES is packaged in bottles containing 60 ml and 150 ml syrup. Each cardboard box contains one bottle containing 60 ml or 150 ml syrup and one 5 ml spoon.
- ALORES is an antiallergic drug that does not cause drowsiness. It helps control your allergic reaction and its symptoms.
- ALORES relieves symptoms such as sneezing, runny nose and itching, itching of the palate and itching, redness and watering of the eyes (eg allergies to hay fever, dust mites).
- ALORES is also used to relieve itching along with urticaria and to eliminate symptoms such as pustules and redness on the skin.
- The effect of relieving these symptoms lasts all day, helping you to continue your normal daily activities and sleeping.

2. What you need to know before you take ALORES

DO NOT take ALORES:

If you are allergic (hypersensitive) to desloratadine, loratadine, or to any of the other ingredients of this medicine.

Warnings and precautions

If you have poor kidney function, talk to your doctor or pharmacist before taking ALORES.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

Use in children and adolescents

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

ALORES with food and drink

ALORES may be taken with or without a meal.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

If you are pregnant, you think that you may be pregnant or plan to have a baby, consult your doctor or pharmacist before taking this medicine.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

ALORES is not recommended if you are pregnant or breastfeeding.

Breast-feeding

ALORES is not recommended if you are breastfeeding.

Consult your doctor or pharmacist before taking this medicine.

Driving and using machines

At the recommended doses, this drug is not expected to affect your ability to drive or use machines. Although most patients do not experience drowsiness, it is recommended that you do not engage in activities that require mental alertness, such as driving or using machines, until you understand your response to the medicinal product.

Important information about some of the excipients of ALORES

ALORES contains sucrose and sorbitol. If you have been previously told by your doctor that you have an intolerance to some sugars, consult your doctor before taking ALORES.

ALORES contains coloring substance FDC yellow no.6 (E110) which may causes allergic reactions.

This medicinal product contains less than 1 mmol (23 mg) sodium. In fact, it is "sodium-free" and does not expect any side effects.

Other medicines and ALORES

There are no known interactions of ALORES with other medicines.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to take ALORE?

- **Instructions for use and dosage/frequency of administration:**

Children 1 through 5 years of age: Take 2.5 ml (½ of a 5 ml spoonful) of syrup once a day.

Children 6 through 11 years of age: Take 5 ml (one 5 ml spoonful) of syrup once a day.

Adults and adolescents (12 years of age and older): Take 10 ml (two 5 ml spoonfuls) of syrup once a day.

You can take this medicine with or without food.

Regarding the duration of treatment, your doctor will determine the type of your allergic rhinitis, also known as hay fever, and tell you how long you should use ALORES.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor will evaluate the history of your illness and offer you a treatment program accordingly.

If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your doctor may recommend you a longer term treatment.

The duration of treatment for hives (urticaria) may vary from patient to patient, so you should follow your doctor's instructions.

- **Route of administration and method:**

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

- **Different age groups:**

- **Use in children:**

- ALORES is used in children 1 year and older.

- **Use in elderly:**

- Efficacy and safety of ALORES has not been established in elderly.

- **Special cases of use:**

- **Hepatic failure:**

- There is no data in patients with hepatic failure.

- **Renal failure:**

- In severe renal failure, ALORES should be used with caution.

If you have impression that the effect of ALORES is very strong or weak, tell a doctor or pharmacist.

- **If you take more ALORES than you should:**

Take ALORES only as it is prescribed for you. No serious problems are expected with accidental overdose.

If you take more ALORES than you should, tell your doctor or pharmacist.

If you forget to take ALORES:

If you forget to take ALORES, take it as soon as possible, then go back to your regular dosing schedule.

Do not take double dose to make up for a forgotten dose.

If you stop taking ALORES:

None.

4. Possible side effects

Like all medicines, ALORES can cause side effects, although not everybody gets them.

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1000 people

Very rare: may affect up to 1 in 10.000 people

Not known: frequency cannot be estimated from the available data

In most adults and children, the side effects of the oral solution were found to be very similar to those of a placebo solution. However, diarrhea, fever and insomnia are more common side effects in children younger than 2 years of age, while fatigue, dry mouth and headache are more common adverse effects in adults than placebo.

In clinical trials with oral solutions, the following side effects have been reported as follows.

Common (in children under 2 years):

- Diarrhea
- Fever
- Insomnia

Common:

- Fatigue
- Dry mouth
- Headache

The following side effects have been reported during marketing.

Very rare:

- Severe allergic reactions
- Rash
- Restlessness with increased body movement
- Palpitations
- Abnormal liver function tests
- Inflammation of the liver
- Dizziness
- Stomache ache
- Nausea (feeling of illness)

- Vomiting
- Diarrhea
- Insomnia
- Drowsiness
- Muscle pain
- Stomach discomfort
- Seizures
- Hallucinations
- Irregular or severe heart beat
- Stroke

Not known

- Increased skin sensitivity to the sun (even when the weather is cloudy) and UV rays (eg UV rays in the solarium)
- Change in heart rate
- Yellowing of skin and / or eyes
- Unusual fatigue

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store ALORES?

Keep this medicine out of the sight and reach of children in the original package.

Store below 25 °C at room temperature.

Use in accordance with expiry date.

Do not use ALORES after the expiry date, which is stated on the package.

Do not use ALORES if you notice any damage in product and/or package.

Marketing authorization holder:

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