

PATIENT INFORMATION LEAFLET

ALORES 2.5mg/5ml 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 PATIENT INFORMATION 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. **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 bottle of 150 ml.
- ALORES is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.
- ALORES relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites). These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.
- ALORES 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. Before you take ALORES

DO NOT take ALORES in following conditions:

If;

- You are allergic (hypersensitive) to desloratadine, loratadine, or to any of the other ingredients of ALORES especially coloring substance FDC yellow no.6 (E110).

ALORES is indicated for children 1 through 11 years of age, adolescents (12 years of age and older), and adults, including the elderly.

TAKE SPECIAL CARE with ALORES:

- if you have poor kidney function.

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

Taking 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 do not use ALORES.

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

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

If you are breast-feeding a baby, do not use ALORES.

Driving and using machines

At the recommended dose, ALORES 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.

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 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.

Taking with other medicines

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 ALORES?

Instructions for proper use and dosage/administration frequency:

Children 1 through 5 years of age: Take 2.5 ml ($\frac{1}{2}$ 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 physician will determine the type of allergic rhinitis (known as hay fever as well) you are suffering from and will determine for how long you should take ALORES.

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.

- **Route and method of administration:**

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

- **Various age groups:**

Children:

ALORES is used in children 1 year and older.

Elderly:

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

- **Special usage condition:**

Liver impairment:

There is no data in patients with liver impairment.

Kidney impairment:

In severe kidney impairment, ALORES should not be used.

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

Do not take double dose to balance the missed doses.

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

If you stop taking ALORES

None.

4. Possible side effects

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

In adults, side effects with ALORES were about the same as with placebo. However, common side effects in children less than 2 years of age were diarrhea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with placebo.

Side effects were listed as shown in the following categories:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

Common:

- fatigue

Uncommon:

- dry mouth
- headache

Very rare:

- allergic reactions (difficulties in breathing, wheezing , itching, urticaria (hives), rash
- hallucinations
- stroke
- restlessness with increased body movement
- palpitations
- fast heartbeat
- abnormal liver function tests
- liver inflammation
- dazedness
- excessively physical and mental state of hyperactivity

- stomach ache, nausea (feeling sick), vomit
- diarrhoea
- insomnia
- drowsiness
- muscle pain
- bloating

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

5. How to store ALORES?

Keep out of the sight and reach of children and store 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 bottle. Do not use ALORES if you notice any damage in product and/or package.

Marketing authorization holder:

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

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