

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

ALLERGYX®

Tablets, 10 mg

Composition

Each tablet contains:
Loratadine 10 mg

For information about inactive ingredients, see section 2, under "Important information about some of the ingredients in this medicine" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about this medicine. If you have further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult a pharmacist if you need further information.

Consult your doctor if your symptoms of illness worsen or do not improve.

1. What is the medicine intended for?

For the relief of allergy symptoms: seasonal and perennial allergic rhinitis with accompanying symptoms: sneezing, itching and watery eyes, as well as for the treatment of allergy of the skin - urticaria.

How does this medicine work?

ALLERGYX relieves your allergy symptoms by preventing the effects of a substance called histamine, which is produced in the body when you are allergic to something.

Therapeutic group: This medicine contains the active ingredient loratadine, which belongs to the group of medicines called "antihistamines".

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to loratadine or to any of the other ingredients in this medicine (for the list of inactive ingredients, see section 6 "Further information").

Special warnings regarding use this medicine

Before treatment with ALLERGYX, tell your doctor or nurse if:

- You have liver disease.

- You are scheduled to have any skin tests for allergies. Do not take ALLERGYX for two days before these tests. This is because the medicine may affect the test results.

If any of the conditions described above apply to you or if you are not sure, consult your doctor, pharmacist, or nurse before taking ALLERGYX.

Children and adolescents

Do not give ALLERGYX to children under 6 years old or to children who weigh less than 30 kg. There are other formulations that are more appropriate for children who are under 6 years old or who weigh less than 30 kg.

Children under 2 years old:

There is no information to show how safe or effective loratadine tablets are in this age group.

Other medicines and ALLERGYX

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor, pharmacist, or nurse.

The risk of side effects is greater when taking ALLERGYX together with medicines that affect the activity of enzymes that are responsible for breaking down medicines in the liver. However, no increase in side effects was observed in clinical trials, even when taking medicines that affect the activity of these enzymes.

Using this medicine and food

You can take ALLERGYX with or without food.

Using this medicine and alcohol consumption

ALLERGYX has not been shown to increase the effects of alcoholic beverages.

Pregnancy, breastfeeding, and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Based on existing data, no harm to unborn babies or newborns was observed after taking this medicine, but it is better to avoid using this medicine during pregnancy.

Loratadine, the active ingredient in this medicine, passes through breast milk so avoid using this medicine while you are breastfeeding.

Driving and using machines

In clinical trials that tested driving ability, no impairment was observed in patients taking loratadine. At the recommended dosage, ALLERGYX is not expected to cause drowsiness or decreased alertness.

Nevertheless, very rarely, some people feel drowsy, which may affect their ability to drive or operate machinery.

Important information about some of the ingredients in this medicine

This medicine contains lactose. Therefore, if you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking it (see also section 6, "Further information").

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The usual dosage is generally:

Adults and children aged 6 years and older who weigh over 30 kg:

One tablet, once a day, with a glass of water, with or without food.

It is important to know how much your child weighs to make sure that you give them the correct dose of medicine. If you are not sure about the child's weight, weigh the child before they take the medicine.

Body weight of 30 kg or less:

Do not give ALLERGYX tablets. There is another formulation that is more appropriate for children who are under 6 years old or who weigh 30 kg or less.

ALLERGYX is not intended for children who are under 2 years old or weigh 30 kg or less.

Adults and children with severe liver problems:

If you have severe liver problems, consult your doctor or pharmacist who may advise you to take the recommended dose every other day, with a glass of water and with or without food. If this applies to you, you must follow their instructions.

Do not exceed the recommended dosage.

Taking the tablets:

These tablets can be split along the score line to ease swallowing, but all the parts of the tablet must be taken at the same time. There is no information about crushing or chewing the tablets.

If you have accidentally taken a higher dosage, consult your doctor or pharmacist immediately.

No severe problems are expected, but you may suffer from headaches, rapid heartbeat, or feel sleepy.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, consult a doctor immediately or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the required time, take a dose as soon as you remember and then continue taking it as usual. Never take a double dose to make up for a forgotten dose.

Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, using ALLERGYX may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The most common side effects reported by adults and children over 12 years of age are:

- drowsiness
- headache
- increased appetite
- difficulty sleeping

The most commonly reported side effects in children aged 2 to 12 years old are:

- headache
- nervousness
- tiredness

Very rare side effects (may affect up to 1 in 10,000 people) have also been seen during the marketing of loratadine:

- severe allergic reaction (including swelling)
- dizziness
- seizure
- accelerated or irregular heartbeat
- nausea
- dry mouth
- digestive system disturbances
- liver problems
- hair loss
- rash
- tiredness

The frequency of the following side effect is not known:

- weight gain

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store this medicine?

• Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor. Do not induce vomiting unless explicitly instructed to do so by a doctor.

• Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

• **Store this medicine in a dry place, below 25°C.**

• Do not take this medicine if you notice any change in the appearance of the tablet.

• Do not throw away medicines into the wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. Further information

In addition to the active ingredient, this medicine also contains: Lactose monohydrate, pregelatinised starch, maize starch, magnesium stearate.

Each tablet contains 62.5 mg lactose monohydrate. See also section 2 "Important information about some of the ingredients in this medicine".

What the medicine looks like and contents of the pack:

An oval, white tablet with a score line that has "L" debossed on one side of it and "10" debossed on its other side. The other side of the tablet is plain.

Approved pack sizes: 7, 10, or 20 tablets in a pack. Not all pack sizes may be marketed.

Registration holder's name and address: Abic Ltd. (Teva Group), P.O.B. 8077, Netanya.

Manufacturer's name and address: Teva Pharmaceutical Industries Private Company Ltd., Debrecen, Hungary.

This leaflet was revised in September 2020.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 124.58.30421

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