

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Loratrim
Syrup

Active ingredient

Each 5 ml contains loratadine 5 mg

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Contact your doctor if your symptoms worsen or do not improve.

1. What is this medicine intended for?

For the treatment of allergic rhinitis and urticaria.

Therapeutic group: antihistamines.

Loratrim helps to reduce your allergy symptoms by stopping the effects of a substance called histamine, which is produced in the body when you are allergic to something.

Loratrim relieves symptoms associated with allergic rhinitis (for example, hay fever), such as sneezing, runny or itchy nose and burning or itchy eyes in adults and children over the age of 2 years. The syrup may also be used to help relieve symptoms of urticaria (itching and redness), which is often known as hives or nettle rash. The effect of Loratrim will last a whole day and should help you to continue your normal daily activities and sleep.

2. Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- If you are pregnant or breast-feeding.

Special warnings about using this medicine

Before using Loratrim, tell your doctor:

- if you have liver disease
- if you are scheduled to have any skin tests for allergies. Do not take Loratrim for two days before these tests. This is because the medicine may affect test results.

If any of the above conditions apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Loratrim.

Children and adolescents

Do not give Loratrim to children below the age of 2.

Interactions with other medicines

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

The side effects of Loratrim may increase when used together with medicines that alter the performance of certain enzymes responsible for drug metabolism in the liver. However, in clinical studies, no

increase in side effects of loratadine was seen when used with medicines that altered the performance of these enzymes.

Using this medicine and food

Water or other liquid is not needed to swallow the syrup. Loratrim may be taken with or without food.

Using this medicine and alcohol consumption

Loratrim has not been shown to add to the effects of an alcoholic drink.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine. As a precautionary measure, it is preferable to avoid the use of Loratrim during pregnancy.

Breast-feeding

Do not take Loratrim if you are breast-feeding. Loratadine is excreted in breast milk.

Driving and using machines

In clinical trials that assessed driving ability, no impairment was observed in patients receiving loratadine. At the recommended dose, Loratrim is not expected to cause drowsiness or reduced alertness. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

Important information about some of this medicine's ingredients

Loratrim contains:

Sugar: This medicine contains 2.6 g sugar in each 5 ml of syrup, a concentration that is equivalent to 520 mg/ml.

If you have been told by your doctor that you (or your child) have an intolerance to some sugars, talk to your doctor before taking this medicine.

Propylene glycol: This medicine contains 500 mg propylene glycol in each 5 ml of syrup, a concentration that is equivalent to 100 mg/ml.

Sodium benzoate: This medicine contains 5 mg sodium benzoate in each 5 ml of syrup, a concentration that is equivalent to 1 mg/ml.

Sodium: This medicine contains less than 1 mmol sodium (23 mg), that is to say essentially 'sodium-free'.

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.

Taking this medicine

- Water or other liquid is not needed to swallow the syrup.
- The syrup may be taken with or without food.

Giving this medicine to children

It is important to know how much your child weighs to make sure that you give the correct amount of medicine. For example, a 9-year-old child weighs about 30 kg. If in doubt, weigh your child and then follow the instructions in the table.

Do not give the medicine to children under 2 years.

How much to take

The recommended dose is:

Age	How much to take	How often to take
Children of 2 to 12 years who weigh 30 kg or less	5 ml (Fill the measuring cup to the 5 ml line)	Once daily

Children of 2 to 12 years who weigh more than 30 kg	10 ml (Fill the measuring cup to the 10 ml line)	Once daily
Adults and children over the age of 12	10 ml (Fill the measuring cup to the 10 ml line)	Once daily

If you have severe liver problems your doctor or pharmacist may recommend that you take the recommended amount every other day. If this applies to you, follow their instructions.

Note:

Use the measuring cup enclosed in the package to measure the correct amount of medicine. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in size, and you may not get the correct amount of the medicine.

Do not exceed the recommended dose.

If you have taken a higher dose of the syrup

If you have taken a higher dose of Loratrim, talk to your doctor or pharmacist straight away. No serious problems are expected; however, you may experience a headache, rapid heartbeat or feel sleepy.

If you forget to take the syrup

If you forget to take your dose, take it as soon as you remember, then continue to take the medicine as usual.

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

If you have any further questions about using this medicine, contact your doctor, pharmacist or nurse.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Loratrim may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

The most commonly reported side effects in 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 through 12 years are:

- headache
- nervousness
- tiredness

The following 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
- convulsion (seizure)
- fast or irregular heartbeat
- nausea
- dry mouth
- upset stomach
- liver problems
- hair loss
- rash
- tiredness

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- 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.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

You may also report by e-mail to: safety@trima.co.il.

5. How to store the 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 your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 25°C in a cool and dark place.

Shelf-life after opening the bottle: 6 months.

Do not use this medicine if you notice any changes in the appearance of the syrup.

- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to dispose of this medicine (medicines you no longer use). These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Sugar, glycerin, propylene glycol, strawberry flavor, sodium benzoate, disodium edetate, citric acid, purified water.

What the medicine looks like and contents of the pack:

Each package contains a bottle with 120 ml of syrup and a measuring cup. A clear, colourless to light yellow syrup.

Manufacturer and registration holder's and address: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in July 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 125.79.30442.00

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

