

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

The medicine is dispensed without  
a doctor's prescription

## LORATRIM Syrup

Each 5 ml contain: Loratadine 5 mg

For the list of inactive ingredients: see section 6, also see section 2, subsection "Important information about some of the ingredients of the medicine".

**Read this leaflet carefully in its entirety before using the medicine.**

- This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
- Refer to the doctor if the signs of the illness (symptoms) worsen or do not improve, or if you feel worse.
- This medicine is not intended for infants and children under the age of 2 years.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of allergic rhinitis and urticaria.

**Therapeutic group:** Antihistamines.

### 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

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

#### Special warnings regarding use of the medicine

**Before treatment with the medicine, tell the doctor if:**

- You are sensitive to any food or medicine.
- You are suffering from a liver disease.
- You are scheduled to have a skin test for allergies. Do not take Loratrim Syrup two days before these tests. This is because the medicine may affect the results of the test.
- Do not use this medicine frequently or for a prolonged period without consulting the doctor.
- If you become pregnant while using this preparation, consult the doctor.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

#### Use of the medicine and food

There is no need for water or another liquid to swallow the syrup.

Loratrim Syrup can be taken with or without food.

#### Use of the medicine and alcohol consumption

It has not been demonstrated that Loratrim Syrup increases the effects of alcoholic beverages.

#### Pregnancy and breastfeeding

If you are pregnant, think you are pregnant, or are planning a pregnancy, consult with the doctor or pharmacist before using the medicine. There is insufficient information regarding the safety of use of this medicine during pregnancy; therefore, use of Loratrim Syrup during pregnancy is not recommended.

The active ingredient of the medicine, loratadine, is secreted into breast milk and harm to newborns or infants cannot be ruled out. Therefore, avoid use of the medicine while breastfeeding.

#### Driving and activity that requires alertness

At the recommended dosage, Loratrim Syrup is not expected to cause drowsiness or decreased alertness. Nevertheless, very rarely, some people feel drowsy, which may affect their ability to drive or to operate machinery.

#### Important information about some of the ingredients of the medicine

Loratrim Syrup contains sucrose; therefore, if you have been told by a doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine (also see section 6, "Further information").

Loratrim Syrup contains sodium benzoate as a preservative.

#### Children

Do not give Loratrim Syrup to infants and children under the age of 2 years.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage is generally:

**Adults and children over 12 years of age:** 10 ml, once a day, with or without food.

**The dosage for children aged 2-12 years is by weight:**

- **Body weight over 30 kg:** 10 ml, once a day, with or without food.
- **Body weight of 30 kg or less:** 5 ml, once a day, with or without food.

Loratrim Syrup is not intended for infants and children under the age of 2 years.

#### Adults and children with severe liver problems:

**Adults and children weighing over 30 kg:** 10 ml, once in two days (one day yes, one day no), with or without food.

**Children weighing 30 kg or less:** 5 ml, once in two days (one day yes, one day no), with or without food.

Nonetheless, refer to your doctor or pharmacist before taking this medicine.

#### Attention:

For liquid medicines, use a measuring teaspoon, syringe or dropper dedicated for measuring the right amount of medicine. If a measuring teaspoon or other measuring utensil has not been provided with the package, consult the pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in size, and you may not get the right amount of medicine.

#### Do not exceed the recommended dose.

If you accidentally took a higher dosage, refer to your doctor or pharmacist immediately.

No severe problems are expected, but you may suffer from a headache, rapid heartbeat, or feeling of sleepiness.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

#### If you forgot to take the medicine:

If you forgot to take this medicine at the required time, take a dose as soon as you remember and continue treatment as per the directions for use. Never take a double dose to compensate for the forgotten dose!

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

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

### 4. SIDE EFFECTS

As with any medicine, use of Loratrim Syrup may cause side effects in some users. Do not be alarmed by 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 2-12 years 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 (manifested by signs such as: skin rash, itching, urticaria, shortness of breath, wheezing or breathing problems, swelling of the face, lips, tongue or other parts of the body)
- dizziness
- fast or irregular heartbeat
- nausea
- dry mouth
- digestive system disturbances
- liver problems (e.g., yellowing of the skin and eyes)
- hair loss
- rash
- tiredness
- seizure

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

#### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il>

Side effects can also be reported to the following email: [safety@trima.co.il](mailto:safety@trima.co.il)

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store in a dark and cool place, below 25°C. After first opening the bottle, can be used for 6 months.
- Do not take this medicine if you notice any change in the way the syrup looks.
- Do not throw medicines into the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

### 6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains inactive ingredients:

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

Each 5 ml contain 2.6 grams sugar and 1.14 mg sodium.

#### What does the medicine look like and what are the contents of the package?

Each package contains a bottle with 120 ml syrup and a measuring cup.

Manufacturer and registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Kibbutz Maabarot 4023000, Israel.

This leaflet was checked and approved by the Ministry of Health in January 2016.

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