

Patient leaflet in accordance with the Pharmacists'

Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Desloratadine-Trima Syrup 0.5 mg/ml

Active ingredient name and concentration

Each 1 ml contains 0.5 mg desloratadine.

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.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

This medicine is intended for the relief of symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) and/or symptoms associated with chronic idiopathic urticaria (a skin condition caused by an allergy) in adults and children 1 year of age and older.

Therapeutic group: H1 receptor antagonists – antihistamines.

The symptoms associated with allergic rhinitis include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes. The symptoms associated with chronic idiopathic urticaria include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

Desloratadine-Trima Syrup does not make you drowsy.

2. Before using this medicine

Do not use this medicine if:

you or your child is sensitive (allergic) to desloratadine or any of the other ingredients in this medicine (see section 6) or to loratadine.

Special warnings about using this medicine

Tell your doctor before starting Desloratadine-Trima Syrup if:

- you or your child has poor kidney function.
- you or your child has a medical or familial history of seizures.

Children and adolescents

This medicine is not intended for children less than 1 year of age.

Interactions with other medicines

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

There are no known interactions of **Desloratadine-Trima Syrup** with other medicines.

Using this medicine and food

You can take **Desloratadine-Trima Syrup** with or without a meal.

Using this medicine and alcohol consumption

Use caution when taking **Desloratadine-Trima Syrup** with alcohol.

Pregnancy, breast-feeding, and fertility

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice

before taking this medicine. Taking **Desloratadine-Trima Syrup** is not recommended if you are pregnant or breast-feeding.

Fertility

There is no information on male/female fertility.

Driving and using machines

At the recommended dose, **Desloratadine-Trima Syrup** is not expected to affect your ability to drive or use machines.

Although most people do not experience drowsiness, it is advisable to avoid activities requiring mental alertness, such as driving a car or operating machines until you know how you respond to the medicine.

Important information about some of this medicine's ingredients
Each 1 ml of **Desloratadine-Trima Syrup** contains 600 mg sucrose and 100 mg sorbitol.

Sorbitol is a source of fructose. If your doctor has told you that you or your child has an intolerance to some sugars or if you or your child has hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, contact your doctor before taking/giving this medicine.

People with diabetes should consider the amount of sucrose in a dose. In addition to this, sucrose can damage teeth.

Each 1 ml of **Desloratadine-Trima Syrup** contains 100 mg propylene glycol.

Desloratadine-Trima Syrup contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dose in children is usually:

Children 1-5 years of age: 2.5 ml once a day.

Children 6-11 years of age: 5 ml once a day.

The recommended dose in adults and adolescents (12 years of age and over) is usually:

10 ml once a day.

This medicine is taken by mouth.

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

Do not exceed the recommended dose.

Attention:

To measure the correct amount of medicine, you must use the measuring cup included in the pack. Do not use a household teaspoon to measure the medicine. Household teaspoons vary in size and you may not get/give the correct amount of medicine. Wash the measuring cup after use.

Treatment duration

Regarding the duration of treatment, your doctor will determine the type of allergic rhinitis you or your child has and will also determine how long you should take **Desloratadine-Trima Syrup**.

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 advise a treatment schedule that will depend on their evaluation of your disease's history.

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 advise treatment for longer.

For urticaria (hives), treatment duration may vary from patient to patient and therefore you should follow your doctor's instructions.

If you have accidentally taken a higher dose

Take **Desloratadine-Trima Syrup** only as you/your child was prescribed. No serious problems are expected with accidental overdose. However, if you take more **Desloratadine-Trima Syrup** than you were told to, tell your doctor or pharmacist immediately.

If a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you.

If you forget to take the medicine

If you forget to take/give the dose on time, take/give it as soon as possible and then go back to your usual dosing schedule. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

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 **Desloratadine-Trima Syrup** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

During the marketing of desloratadine, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) were reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies, side effects with desloratadine in most children and adults were about the same as those reported with dummy (placebo) syrup or tablets. However, in children under two years old the common side effects were diarrhoea, fever and difficulty sleeping, while in adults, tiredness, dry mouth, and headache were reported more commonly than with dummy (placebo) tablets.

Additional side effects

In clinical studies with desloratadine, the following side effects were reported as:

Common side effects – affecting up to 1 in 10 users:

tiredness; dry mouth; headache.

In children

Common side effects in children less than 2 years of age: affecting up to 1 in 10 users:

diarrhoea; fever; difficulty sleeping.

During the marketing of desloratadine, the following side effects were reported as:

Very rare side effects - affecting up to 1 in 10,000 users:

severe allergic reactions; rash; pounding or irregular heartbeat; fast heartbeat; stomach ache; nausea; vomiting; upset stomach; diarrhoea; dizziness; drowsiness; inability to sleep; muscle pain; hallucinations; seizures; restlessness with increased body movement; liver inflammation; abnormal liver function tests.

Side effects of unknown frequency (side effects whose frequency has not been established yet):

unusual weakness; yellowing of the skin and/or eyes; increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV

light, for instance to UV lights of a solarium (tanning salon); changes in the way the heart beats; abnormal behaviour; aggression; weight increased, increased appetite; depressed mood; dry eyes.

Children

Side effects of unknown frequency (side effects whose frequency has not been established yet):

slow heartbeat; changes in the way the heart beats; abnormal behaviour; aggression.

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 can also report side effects by email: 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.
- Store in a cool place, below 25°C.
- Use within 6 months of first opening.
- Do not use this medicine if you notice any change in the appearance of the syrup.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away 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: Sucrose, sorbitol, propylene glycol, sodium citrate dihydrate, citric acid anhydrous, disodium edetate, purified water.

What the medicine looks like and contents of the pack:

The syrup is packed in a bottle containing 120 ml with a childproof cap.

The bottle contains a clear, pale-yellow liquid.

Manufacturer and registration holder's name and address:

Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in September 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 150.37.33827.00

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

