

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

This medicine can be sold under doctor's prescription only

**DES Loratadine- TRIMA SYRUP**

**Active ingredient name and quantity:**

Each 1 ml contains: desloratadine 0.5 mg.

For a list of inactive ingredients see section 6.1 "What **DES Loratadine- TRIMA SYRUP** contains". See also section 2.7 "Important information about some of the ingredients of **DES Loratadine- TRIMA SYRUP**".

**Read all of this leaflet carefully before you start using this medicine.**

- This leaflet contains concise information about **DES Loratadine- TRIMA SYRUP**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their medical condition seems similar to yours.
- **DES Loratadine- TRIMA SYRUP** does not make you drowsy. This medicine is not intended for children below one year of age.

**1. WHAT DES Loratadine- TRIMA SYRUP IS AND WHAT IT IS USED FOR**

This medicine is indicated 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 the symptoms associated with chronic idiopathic urticaria (a skin condition caused by an allergy) in adults, adolescents and children 1 year of age and older.

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.

**Therapeutic group:** H<sub>1</sub> receptor antagonists - antihistamines.

**2. BEFORE YOU USE DES Loratadine- TRIMA SYRUP**

**2.1. Do not use DES Loratadine- TRIMA SYRUP if you:**

are allergic (hypersensitive) to desloratadine or to any of the other ingredients of **DES Loratadine- TRIMA SYRUP** or to loratadine (for a list of inactive ingredients, see section 6.1).

**2.2. Special warnings concerning use of DES Loratadine- TRIMA SYRUP**

**Before starting treatment with DES Loratadine- TRIMA SYRUP, tell the doctor if:**

- you have poor kidney function.
- you have a medical or familial history of seizures.

**2.3. Drug interactions**

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

There are no known interactions of **DES Loratadine- TRIMA SYRUP** with other medicines.

**2.4. Taking DES Loratadine- TRIMA SYRUP with food, drink and alcohol**

**DES Loratadine- TRIMA SYRUP** may be taken with or without a meal. Use caution when taking **DES Loratadine- TRIMA SYRUP** with alcohol.

**2.5. Pregnancy, breast-feeding and fertility**

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 **DES Loratadine- TRIMA SYRUP** is not recommended if you are pregnant or nursing a baby.

**Fertility** - There is no data available on male/female fertility.

**2.6. Driving and using machines**

At the recommended dose, **DES Loratadine- TRIMA SYRUP** is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

**2.7. Important information about some of the ingredients of this medicine**

**DES Loratadine- TRIMA SYRUP** contains sucrose and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**2.8. Use in children and adolescents**

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

**3. HOW TO USE DES Loratadine- TRIMA SYRUP?**

Always use **DES Loratadine- TRIMA SYRUP** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure. The dosage and duration of treatment will be determined by the doctor only.

**The recommended dose for children is usually:**

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

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

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

10 ml once a day.

This medicine is for oral use.

Swallow the medicine and then drink some water. The medicine may be taken with or without food. **Do not exceed the recommended dose.**

**Note:**

When using liquid medicines, use a measuring cup, syringe, or dropper that are specially made for measuring the correct amount of the medicine. Please consult your pharmacist about getting a suitable measuring utensil. Do not use a household teaspoon to measure the medicine. Household teaspoons vary in size and you may not get the correct amount of medicine.

Childproof caps have significantly reduced the number of poisoning cases caused by medicines every year. If it is difficult for you to open the package, please ask the pharmacist for help.

Regarding the duration of treatment, your doctor will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take **DES Loratadine- 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 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 doctor 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 the doctor.

**If you take more DES Loratadine- TRIMA SYRUP than you should**

Take **DES Loratadine- TRIMA SYRUP** only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more **DES Loratadine- TRIMA SYRUP** than you were told to, tell your doctor or pharmacist immediately.

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

**If you forget to take DES Loratadine- TRIMA SYRUP**

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

Complete the full course of treatment as instructed by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting the doctor.

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

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

**4. SIDE EFFECTS**

Like all medicines, the use of **DES Loratadine- TRIMA SYRUP** can cause side effects, in some of the users. Do not be alarmed by reading the list of side effects; you may not suffer from any of them.

During the marketing of desloratadine, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been 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 in most children and adults, side effects with desloratadine were about the same as with a dummy syrup or tablet. However, common side effects in children less than 2 years of age were diarrhoea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

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

Children

Common in children less than 2 years of age: the following may affect up to 1 in 10 children: Diarrhoea; fever; insomnia.

Adults

Common: the following may affect up to 1 in 10 people: Fatigue; dry mouth; headache.

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

Adults

Very rare: the following may affect up to 1 in 10,000 people:

Severe allergic reactions; rash; pounding or irregular heartbeat; fast heartbeat; stomach ache; feeling sick (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.

Not known: frequency cannot be estimated from the available data:

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; change in the way the heart beats, abnormal behaviour, aggression, weight increased, increased appetite.

Children

Not known: frequency cannot be estimated from the available data:

Slow heartbeat; change in the way the heart beats, abnormal behaviour, aggression.

If a side effect appears, if any of the side effects gets serious, or if you notice a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site ([www.health.gov.il](http://www.health.gov.il)) which refers to the online form for reporting side effects, or by using the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

You can also report side effects by email: [safety@trima.co.il](mailto:safety@trima.co.il)

**5. HOW TO STORE DES Loratadine- TRIMA SYRUP?**

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use **DES Loratadine- TRIMA SYRUP** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated 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.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**6.1. What DES Loratadine- TRIMA SYRUP contains**

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

Sucrose, sorbitol, propylene glycol, sodium citrate dihydrate, citric acid anhydrous, disodium edetate, purified water.

Each 5 ml contains 3 grams of sugar and 6.1 mg of sodium.

**6.2. What DES Loratadine- TRIMA SYRUP looks like and contents of the pack.**

The syrup is packaged in a 120 ml bottle, with a safety cap.

**Name and address of the registration holder:**

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

**Drug registration no. listed in the official registry of the Ministry of Health:** 150.37.33827.00

This leaflet was checked and approved by the Ministry of Health in August 2013 and was updated according to Ministry of Health instructions in August 2018.

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Israel Pharmaceutical Products  
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