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

This medicine can be sold under doctor's prescription only

# DESLORATADINE- TRIMA TABLETS

**Each tablet contains:** desloratadine 5 mg

For a list of inactive ingredients please refer to section 6 "**What do DESLORATADINE- TRIMA TABLETS contain**".

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

- This leaflet contains concise information about **DESLORATADINE- TRIMA TABLETS**. 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 ailment seems similar to yours.
- This medicine is intended for adults and adolescents 12 years of age and older.

## 1. WHAT IS DESLORATADINE- TRIMA TABLETS INTENDED FOR?

**DESLORATADINE- TRIMA TABLETS** is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

This medicine relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults and adolescents 12 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

**DESLORATADINE- TRIMA TABLETS** is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms 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:** $H_1$ receptor antagonists - antihistamines.

## 2. BEFORE YOU USE DESLORATADINE- TRIMA TABLETS

### 2.1. Do not use DESLORATADINE- TRIMA TABLETS if you:

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

### 2.2. Special warnings concerning use of DESLORATADINE- TRIMA TABLETS

**Before starting treatment with DESLORATADINE- TRIMA TABLETS, 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 any other medicines including non-prescription drugs and food supplements, consult your doctor or pharmacist.**

There are no known interactions of **DESLORATADINE- TRIMA TABLETS** with other medicines.

### 2.4. Taking DESLORATADINE- TRIMA TABLETS with food, drink and alcohol

**DESLORATADINE- TRIMA TABLETS** may be taken with or without a meal.

Use caution when taking **DESLORATADINE- TRIMA TABLETS** 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 **DESLORATADINE- TRIMA TABLETS** is not recommended if you are pregnant or breast-feeding.

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

### 2.6. Driving and using machines

At the recommended dose, **DESLORATADINE- TRIMA TABLETS** 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. Use in children and adolescents

This medicine is not intended for children under the age of 12.

## 3. HOW DO YOU USE DESLORATADINE- TRIMA TABLETS?

Always use **DESLORATADINE- TRIMA TABLETS** as instructed by the doctor. Check with your doctor or pharmacist if you are unsure. The dosage and duration of treatment will be determined by the doctor only.

**Adults and adolescents (12 years of age and older)**

The usually recommended dose is one tablet once a day with water, with or without food.

**Do not exceed the recommended dose**.

This medicine is for oral use.

Swallow the tablet whole.

There is no score line, so do not split the tablets. No information is available with regards to crushing/chewing.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take **DESLORATADINE- TRIMA TABLETS**.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician 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 physician 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 your physician.

**If you take more DESLORATADINE- TRIMA TABLETS than you should** Take **DESLORATADINE- TRIMA TABLETS** only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more **DESLORATADINE- TRIMA TABLETS** 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, immediately refer to a doctor or to a hospital's emergency room and bring the medicine's package with you.

**If you forget to take DESLORATADINE- TRIMA TABLETS**

If you forgot to take **DESLORATADINE- TRIMA TABLETS** 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 a forgotten dose.

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

Even if there is an improvement in your condition, do not discontinue use of this medicine, without consulting your doctor or pharmacist.

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 any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. SIDE EFFECTS

Like all medicines, the use of **DESLORATADINE- TRIMA TABLETS** 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 adults, side effects were about the same as with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet. In adolescents, headache was the most commonly reported side effect.

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

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

Adults

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

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) 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 may also report side effects to Trima by email: Safety@trima.co.il

## 5. HOW TO STORE DESLORATADINE- TRIMA TABLETS?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Store in a dry place below 25ºC. Store in the original package.
- Do not use **DESLORATADINE- TRIMA 5 mg TABLETS** after the expiry date (exp. date) which is stated on the blister and outer carton. The expiry date refers to the last day of the indicated month.
- Do not use this medicine if you notice any change in the appearance of the tablets.
- 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 Do DESLORATADINE- TRIMA TABLETS contain?

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

Microcrystalline cellulose, calcium hydrogen phosphate anhydrous, magnesium stearate, HPMC, titanium dioxide, polyethylene glycol, FD&C blue No.1 aluminium lake.

### 6.2. What DESLORATADINE- TRIMA TABLETS looks like and content of the pack

Round, pale blue, film-coated tablet.

The product is available in two package sizes: 15 or 30 tablets.

**Manufacturer and Registration Holder:**

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

**Drug registration no. listed in the official registry of the Ministry of Health:** 149-99-33681-00

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

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**Maabarot 4023000**
**Israel Pharmaceutical Products**
**Maabarot Ltd.**

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