

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

The dispensing of this medicine requires a doctor's prescription

Tinden drops

Active ingredient and its quantity per dosage unit:

1 ml contains 1 mg dimetindene maleate
(each drop contains 0.05 mg)
dimetindene maleate 1 mg/ml

Inactive ingredients and allergens: See chapter 2, section: 'Important information about some of this medicine's ingredients' and chapter 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.

The medicine is not intended for infants below the age of 1 month.

1. What is this medicine intended for?

Tinden drops is an anti-pruritic, antihistamine and anti-allergic medicine.

Therapeutic group: The medicine belongs to the antihistamines class.

Tinden drops are intended for oral use.

2. Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient dimetindene maleate or to any of the other ingredients that this medicine contains.
- In infants below the age of 1 month, especially preterm infants.

In such cases, talk to your doctor or pharmacist since this means that **Tinden drops** is not suitable for you.

Special warnings regarding using this medicine

Before you start taking Tinden drops, tell your doctor if you suffer from:

- glaucoma
- urinary retention (for example, due to enlargement of the prostate gland)
- epilepsy
- chronic obstructive pulmonary disease or any other illness

Children and adolescents

Tinden drops should be used in young children aged 1 month to 1 year only according to the doctor's recommendation. Do not exceed the recommended dose. The sedative effect may be accompanied by pauses in breathing during sleep. Anti-histamines may trigger agitated states, especially in children.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications, dietary supplements and medicines for external use, tell your doctor or pharmacist. Particularly tell your doctor or pharmacist prior to starting treatment with **Tinden drops** if you are taking:

- antidepressants (MAO inhibitors or tricyclic antidepressants)
- anticholinergics such as bronchodilators (medicines used to treat asthma or bronchospasm) gastrointestinal antispasmodics (medicines for cramps in the stomach or intestines), mydriatics (medicines to dilate the pupils), urological antispasmodics (medicines to treat symptoms of urinary incontinence or overactive bladder)
- medicines suppressing the central nervous system (such as sedatives or sleeping drugs)
- anti-epileptic drugs
- opiate analgesics (strong painkillers)
- antihistamines (medicines used for cough, cold or allergy)
- antiemetics (medicines to stop vomiting)
- procarbazine (a medicine to treat certain types of cancer)
- scopolamine (a medicine to prevent motion sickness)

Using this medicine and alcohol consumption

Similarly to other antihistamines, **Tinden drops** may increase the effect of alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think that you are pregnant or planning to become pregnant, consult your doctor before taking this medicine.

Taking **Tinden drops** is not recommended during the breastfeeding period.

Driving and using machines

Caution is required while driving or operating dangerous machines during treatment with this medicine since the medicine may cause a sensation of tiredness or impair alertness. Children should be warned against driving bicycles or playing near highways, etc.

Important information about some of this medicine's ingredients

Each 1 ml of the medicine contains 1 mg benzoic acid and 100 mg propylene glycol.

3. How to use this medicine?

Always use this medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how you should use this medicine. Only your doctor will determine your dose and the manner of treatment. The commonly used dose is usually:

Adults and children aged over 12 years:

20-40 drops, 3 times per day.

Children:

In children aged 1 month up to 1 year, **Tinden drops** should be used only according to the doctor's recommendation.

The commonly used daily dose is:

2 drops/kg body weight per day, divided into 3 doses.

Age/weight	Dose in drops
1 month - 1 year / 4.5 - 15 kg	3 - 10 drops, 3 times per day
1 - 3 years / 15 - 22.5 kg	10 - 15 drops, 3 times per day
3 - 12 years / 22.5 - 30 kg	15 - 20 drops, 3 times per day

Do not exceed the recommended dose.

Tinden drops are heat-sensitive. Therefore, add the drops into a lukewarm feeding bottle at the last moment. If the child is already able to eat with a spoon, give him/her the drops undiluted with a teaspoon.

If you have taken too much of Tinden drops: contact your doctor or pharmacist immediately.

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

If you have forgotten to take a dose: Take **Tinden drops** as soon as you remember, unless the next dose is due in less than 2 hours. In this case, you should not take the forgotten dose, but take the next dose at the usual time according to the dosage schedule. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor. If you believe that the effect of the medicine is too weak or too strong, contact your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose each time you take the 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

Like all medicines, using **Tinden drops** may cause side effects in some people. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Stop taking **Tinden drops** and tell your doctor immediately if you experience any of the following symptoms, which may be signs of an allergic reaction:

- difficulties breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin with a red rash or blisters
- muscle spasms

These side effects are very rare (occurring in less than 1 in 10,000 users).

Additional side effects

Other side effects are usually mild and transient. They occur mainly at the beginning of treatment.

Very common side effects (affect more than one in ten users):

Tiredness

Common side effects (affect 1-10 in 100 users):

Drowsiness, nervousness

Rare side effects (affect 1-10 in 10,000 users):

Restlessness, headache, dizziness, gastrointestinal disorders such as vomiting, dry mouth or dry throat.

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.

Reporting side effects

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Medication" on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects.

You can also use this link: <https://sideeffects.health.gov.il>

You can also report side effects by email 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 reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store the medicine in a cool place below 25°C. Do not freeze.
- After first opening of the bottle, the medicine can be used for 6 months and no later than the expiry date.

6. Additional information

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

propylene glycol, citric acid anhydrous, sucralose, benzoic acid, trisodium citrate, disodium edetate, purified water.

What the medicine looks like and what are the contents of the package:

A clear and transparent solution.

Each bottle contains 20 ml of solution.

Name of the manufacturer and the registration holder:
Trima Israel Pharmaceutical Products Maabarot Ltd.,
Maabarot 4023000, Israel

This leaflet was revised in November 2021 according to MOH guidelines

Registration number of the medicine in the Ministry of Health's National Drug Registry: 160-63-35127-00

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

