

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

This medicine is dispensed without a doctor's prescription

Tinden Gel

Name and quantity of active ingredient in a unit dose:

1 gram of gel contains 1 mg dimetindene maleate
dimetindene maleate 1mg/gram

Inactive ingredients and allergens: See Section 2 '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, see your doctor or pharmacist.

Use this medicine according to the instructions mentioned in the dose section of this leaflet. Consult your pharmacist if you need further information. See your doctor if symptoms of illness get worse or do not improve within 7 days.

1. What is this medicine intended for?

Rash, itching, non-inflammatory skin diseases, burns, insect bites, allergic skin inflammation, and eczema.

Therapeutic group: antihistamine.

Dimetindene maleate inhibits the activity of histamine, one of the substances that is released during allergic reactions.

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 cases of known allergies to insect bites.
- On open or inflamed wounds, on weepy skin disorders, on mucous membranes or near the eyes (especially in babies and small children).

Special warnings concerning the use of this medicine

Avoid using over large skin areas, especially in babies and small children. Avoid extended exposure of the treated areas to sunlight. Consult a doctor if you have a very severe itch or skin lesions that affect large areas of skin.

Tinden Gel contains propylene glycol so it may cause local skin irritations.

Consult your doctor if your symptoms persist for longer than seven days.

Tell your doctor if you have any other disease, if you are allergic, especially to other medicines, if you are already taking other medicines orally or applying them externally.

Drug interactions

If you are taking or have recently taken other medicines,

including prescription medications, dietary supplements, and medicines for external use, tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility

Use **Tinden Gel** with caution during pregnancy and breastfeeding and do not apply it to large areas of skin, or broken or inflamed skin. Do not use the gel on your nipples while you are breastfeeding.

Driving and using machines

This medicine has a negligible effect or has no effect on your ability to drive or use machines.

Important information about some of this medicine's ingredients

Tinden Gel contains propylene glycol so it may cause local skin irritation.

Tinden Gel also contains benzalkonium chloride which can cause local irritation as well. You should not apply this medicine to the breasts if you are breast-feeding because the baby may take it in with your milk.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dose is usually:

Adults and children:

Apply 2-4 times a day to the affected area or as needed.

Do not exceed the recommended dose.

This medicine is for external use only.

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

Be sure to take the dose listed in the patient leaflet or follow your doctor's instructions. If you think that the effect of the medicine is too weak or too strong, see 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 Gel** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using **Tinden Gel** and consult your doctor or pharmacist if you notice any of the following symptoms:

Uncommon side effects (occur in 1-10 in 1,000 users): dry skin or burning sensation.

Very rare side effects (occur in less than one in 10,000 users): allergic skin reactions including rash and itching.

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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.
- Shelf-life after first opening: 6 months.

Storage conditions

- Store this medicine in a cool place below 25°C.

6. Additional information

In addition to the active ingredient this medicine also contains: Propylene glycol, carbomer homopolymer type B, disodium edetate, benzalkonium chloride, sodium hydroxide, purified water.

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

A colourless, clear to slightly opalescent homogeneous gel. Each package contains 30 grams or 100 grams. Not all pack sizes may be marketed.

License holder name and address:

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

Manufacturer name and address:

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

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Registration number of the medicine in the Ministry of Health National Drug Registry: 160-62-34854-00

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

