

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without doctor's prescription

Histafed Film coated tablets / Syrup

Histafed Film coated tablets: each film coated tablet contains:

Triprolidine HCl 2.5mg

Pseudoephedrine hydrochloride 60mg

Histafed syrup: each 5 ml contains:

Triprolidine HCl 1.25mg

Pseudoephedrine hydrochloride 30mg

Inactive ingredients in the preparations - see section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about this medicine. If you have any further questions, refer to the doctor or the pharmacist.

This medication is not intended for infants under one year of age and is not recommended for children under 6 years of age. Children from 1-6 years of ages should be given this medication by prescription only.

For children below 12 years of age the medicine should be taken in the syrup form. Use the medication correctly. Consult a pharmacist if more information is required. Refer to the doctor if the signs of the illness (symptoms) get worse or do not improve after 7 days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Therapeutic activity:

For the symptomatic relief of nasal congestion in case of rhinitis and associated allergic conditions.

Therapeutic group:

Triprolidine is an H1-antihistamine.

Pseudoephedrine is an alpha-agonist.

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- you are sensitive to the active ingredients or to any of the other ingredients that this medicine contains (see section 6).
- in infants under one year of age.
- you are pregnant and/or breastfeeding.
- you are being treated concomitantly with medicines from the monoamine oxidase inhibitors (MAOI) group (for treatment of depression), or within 14 days of stopping treatment with this group of medicines.
- you are experiencing an asthmatic attack.
- you suffer from heart diseases such as: ischemic heart disease, Coronary artery disease, occlusive vascular disease or hypertension.
- you suffer from diabetes.
- you suffer from severe kidney function impairment.
- you suffer from a pheochromocytoma (a rare tumor of the adrenal glands).
- you suffer from an overactive thyroid gland.
- you suffer from glaucoma.
- you suffer from an enlarged prostate gland and/or urinary retention.
- you are taking other medicines to treat congestion including nasal sprays.

▲ Special warnings regarding use of the medicine

- For children over one year and under 6 years of age, consult a doctor before using the medicine.
- The use of this medicine may cause blurring of vision.
- Do not use this medicine frequently, or for a long period, without consulting a doctor.
- Avoid drinking alcoholic beverages and/or using other drugs which cause drowsiness (such as sedatives) while taking Histafed, as the effect of alcohol and/or sedatives may be intensified by the use of Histafed.
- Histafed contains pseudoephedrine. Before starting to use any additional medication (prescription or over the counter medication), check the list of ingredients to find out if the new medicine contains pseudoephedrine. If it does, or if you are not sure, consult your doctor or pharmacist.
- Do not start a new diet while taking Histafed, and avoid taking appetite suppressants without consulting a doctor.
- If you are experiencing sleeping difficulties while using Histafed consult your doctor or pharmacist regarding the best time to take the medication.
- Caution is advised when the medication is administered to elderly people, as they may be more sensitive to the medication's effects.
- Beware of the possible involvement of excitability when Histafed is being administered to children.

▲ Do not use this medicine without consulting a doctor before beginning treatment if:

- you suffer or have suffered from impaired function of the respiratory system (such as asthma), heart, liver, kidney / urinary tract, gastrointestinal tract (such as stomach ulcers, obstruction of the stomach or intestine), seizures, sleep related breathing difficulties, sleeping difficulties, breathing problems (such as asthma, emphysema, chronic bronchitis), Porphyria (blood disease).
- The cough is accompanied by high fever, persistent headaches, dizziness or rash.
- you are about to undergo surgery, due to a possible reaction with anesthetics.
- you are sensitive to any type of food or medicine.

▲ If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, inform your doctor or pharmacist. In particular inform the doctor or the pharmacist if you are taking:

- medicines affecting the central nervous system (e.g. sedatives, hypnotics, drugs for epilepsy, drugs for treatment of allergies, surgical anesthetics and narcotic analgesics).
- medicines for treatment of depression (e.g., monoamine oxidase inhibitors MAOI).
- antihypertensive and heart medications (e.g. beta blockers, diuretics).
- anticholinergic drugs.
- other sympathomimetics medicines to treat cough and cold (e.g. to reduce congestion).
- appetite suppressants (e.g. amphetamines).
- medicines that stimulate the nervous system (e.g., medicines used to treat narcolepsy or medicines used to treat attention deficit disorder ADD).
- Antipsychotics medicines.
- Digoxin, Quinidine.
- medicines to treat Parkinson's disease (selegiline and rasagiline).
- medicines to treat migraine (ergot alkaloids).
- antacids (kaolin and aluminium hydroxide).
- apraclonidine (medicine for glaucoma).
- Oxitocin.

▲ Using the medicine and food

Histafed may be taken with or without food. If stomach upset occurs, take with food or milk.

▲ Using the medicine and alcohol consumption

Do not drink wine or any other alcoholic beverages while using the medicine.

▲ Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not use this product.

If you become pregnant while using Histafed, consult your doctor immediately.

▲ Driving and using machines

Use of this medicine may impair alertness and therefore caution should be exercised when driving a car, operating dangerous machinery and in any other activity which requires alertness. Children should be cautioned against bicycle riding, playing near roads and the like.

▲ Important information regarding some of the ingredients of the medicine

The syrup preparations contain sucrose. If you are known to suffer from any kind of sugar intolerance, consult your doctor prior to using the medication.

3. HOW SHOULD YOU USE THE MEDICINE?

You should check with the doctor or the pharmacist if you are unsure.

The usual acceptable dosage is:

Tablets:

Adults and children over 12 years of age:

One tablet every 4- 6 hours. Do not take more than 4 tablets within 24 hours.

Swallow the tablets with a small amount of water.

As there is no score line, do not split the tablets. There is no information about crushing/chewing.

Children below 12 years of age:

The medicine should be taken in the syrup dosage form.

Syrup:

Adults and children above 12 years of age:

10 ml every 4-6 hours. Do not exceed the dosage of 4 doses (40 ml) in 24 hours.

Children 6-12 years of age:

5 ml every 6-8 hours. Do not exceed the dosage of 4 doses (20 ml) in 24 hours.

Children from one year to 6 years of age:

Dosage will be determined according to the doctor's instruction.

This medicine is not intended for administration to infants under one year of age.

Attention:

With liquid medications, you must use a measuring cup, syringe or dropper meant for measuring the correct amount of medicine. Consult a pharmacist in order to choose an appropriate measuring device. Do not use a household spoon to measure the amount of the medicine. Household spoons differ in size and you may not get the correct amount of medicine.

In order to minimize insomnia, the last daily dose should be taken a few hours before bedtime.

Duration of treatment: Consult the doctor if signs of the illness (symptoms) worsen or if they do not improve after 7 days.

Do not exceed the recommended dose.

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

In case of an overdose you may feel following symptoms: bluish-colored skin, difficulty breathing, dilated pupils, fast or irregular heartbeats, fever, flushing, hallucinations, mental or mood changes, seizures, severe drowsiness or

dizziness, severe excitability, severe nausea or vomiting, sweating, tremors.

If you forget to take your medication on time, take the dose as soon as you remember; but if it is almost time for the next dose, skip the forgotten dose and take the next dose at the usual time. Never take a double dose!

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

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

4. SIDE EFFECTS

As with any medicine, use of Histafed may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor immediately if the following affects develop:

- Shortness of breath or breathing difficulties, fever, swelling of the face, neck, mouth, tongue lips or throat, severe rash, stomach pain (may indicate a severe allergic reaction).
- Heart rhythm disturbances, palpitations, high blood pressure.
- Anxiety, tremors.
- Urinary retention (in men).
- Skin rash.
- Continuous headaches and sore throat.
- Hallucinations and paranoia (rare), reported especially in children.

Refer to the doctor immediately if the following effects occur:

- nervousness, restlessness, sleeping disturbances.
- nausea or vomiting.
- headache.
- dry mouth, nose or throat.
- blurred vision.
- chest pain.
- decrease coordination.
- difficulty urinating.
- fever.
- convulsions.
- severe dizziness and drowsiness.
- unusual tiredness.

Additional side effects:

- Glaucoma (increased intraocular pressure).
- Blood circulation problems (such as feeling a cold sensation in the hands and feet).
- Drowsiness, dizziness, fatigue, excitability (especially in children).
- Stomachache, constipation, diarrhea.

Adverse reactions and drug interactions in children and infants:

Parents must inform the attending doctor about any side effects, as well as any additional medicine given to the child! See above for details of special side effects and drug interactions.

If a side effect occurs, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link:

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

Side effects can be also reported by email: safety@trima.co.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a close place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/blister/label. The expiry date refers to the last day of that month.
- Use this medicine within 6 months of first opening the bottle.
- Tablets: Store in a dry place, below 25°C.
- Syrup: Store in a cool and dark place, below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the preparations also contain the following inactive ingredients:

Histafed tablets:

Dicalcium phosphate dihydrate, microcrystalline cellulose, maize starch, povidone, magnesium stearate, colloidal silicon dioxide, pregelatinized starch, HPMC, titanium dioxide, polyethylene glycol, erythrosine aluminium lake, quinoline yellow aluminium lake.

Histafed syrup:

Sucrose, purified water, glycerol, strawberry flavor, saccharine sodium, methyl hydroxybenzoate sodium, citric acid anhydrous, propyl hydroxybenzoate sodium.

Each 5 ml contains 3 g sucrose and 2.5 mg sodium.

- **What does the medicine look like and what are the contents of the package:**

Histafed Tablets: The package contains 20 round red-film coated tablets.

Histafed Syrup: A bottle with 115 ml of syrup and a measuring cup.

- **Manufacturer and registration holder:** Trima Israel Pharmaceutical Products Ltd., Maabarot 4023000, Israel.
- This leaflet was checked and approved by the Ministry of Health in: March 2016
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Histafed tablets: 027 94 21825 00
Histafed syrup: 107 14 21824 00

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**Maabarot 4023000
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