

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

The medicine is dispensed with a doctor's prescription only

Histafed Compound Linctus Syrup

Each 5 ml contains:

Tripolidine HCl	1.25 mg
Pseudoephedrine hydrochloride	30 mg
Codaine phosphate	5 mg

For inactive ingredients in the preparation – see section 6 “Further Information”.

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

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

The medicine is not recommended for children and adolescents aged 12-18 suffering from respiratory problems.

The medicine is not intended for those who are known to produce significant quantities of morphine following a dose of codeine (they belong to the group of “CYP2D6 ultra-rapid metabolizers”), since they are at increased risk of suffering from severe side effects as a result of taking codeine.

1. WHAT IS THE MEDICINE INTENDED FOR?

Antitussive when accompanied with nasal and upper respiratory tract congestion.

Therapeutic group:

Tripolidine is an H1 antihistamine.

Pseudoephedrine is an alpha agonist.

Codaine Phosphate is an opiate cough suppressant.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- You are sensitive to the active ingredients or to other members of the opiate family or to any of the additional ingredients contained in the medicine (see section 6).
- Do not use in children under the age of 12.
- The medicine is not intended for those who are known to produce significant quantities of morphine following a dose of codeine (they belong to the group of “CYP2D6 ultra-rapid metabolizers”), since they are at increased risk of suffering from severe side effects as a result of taking codeine.
- You are pregnant and/or breastfeeding.
- You suffer from epilepsy.
- You suffer from severe hypertension, problems with coronary arteries and/or urinary retention.
- You suffer from glaucoma (increased intraocular pressure).
- You suffer from a peptic ulcer.
- Do not use during an asthmatic attack or respiratory depression.
- You suffer from a persistent or chronic cough due to smoking, asthma, emphysema or if the cough is accompanied by excessive phlegm.
- You are concurrently being treated with monoamine oxidase inhibitors, MAOI, (for treatment of depression) or within 14 days of the termination of such treatment.
- You are suffering from heart diseases such as: ischemic heart disease, occlusive vascular disease or hypertension.
- You suffer from diabetes.
- You suffer from severe impairment of kidney function.

- You suffer from a pheochromocytoma (a rare tumor of the adrenal gland).
- You suffer from hyperactivity of the thyroid gland.
- You suffer from an enlarged prostate gland.
- You are being treated concomitantly with other medicines, including nasal sprays, for treatment of congestion.
- You are being treated concomitantly with furazolidone (an antibiotic).
- You are suffering, or have suffered in the past, from liver insufficiency, head injury, intracranial pressure, intestinal blockage, alcoholism, diarrhea as a result of poisoning or due to antibiotics.
- Do not use in children and adolescents between the ages of 12-18 after tonsillectomy or adenoidectomy performed to treat obstructive sleep apnea.

Special warnings regarding use of the medicine:

- The medicine is not recommended for children and adolescents aged 12-18 suffering from respiratory problems.
- Naturally and rarely, in some people codeine undergoes metabolism more rapidly than in most people. In these rare cases high levels of metabolites may accumulate and can cause severe side effects, such as: breathing difficulties, dizziness, extreme somnolence, confusion. In such cases refer immediately for medical care.
- Prolonged use may cause dependence!
- Use of this medicine may cause blurring of vision.
- Do not use this medicine frequently or for a prolonged period without consulting a doctor.
- It is recommended to use with caution in elderly patients, since side effects may develop more frequently in these patients.

❗ Do not use the medicine without consulting the doctor before beginning treatment if:

- You suffer, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma), the heart and/or vascular system, the eyes (e.g., glaucoma), the liver, the kidney/urinary tract, the digestive system (e.g., an ulcer, diarrhea, colitis, intestinal inflammation, severe bloody diarrhea), the thyroid gland, the prostate gland (prostate enlargement, difficulty or increased frequency in passing urine), diabetes or sugar intolerance, hypertension, brain injury, Addison's disease, gall bladder disease or gall bladder stones, convulsions, epilepsy, weakness, muscle weakness (myasthenia gravis), hypotension or in a state of shock, drug or medicine addiction, mental diseases.
- You are about to undergo surgery, because of possible reaction with the anesthetics.
- You are sensitive to any food or medicine.

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

- In particular, inform the doctor or pharmacist if you are taking:
 - Medicines affecting the central nervous system (e.g., sedatives, hypnotics, antiepileptics).
 - Antidepressants (e.g., monoamine oxidase inhibitors - MAOI, tricyclic antidepressants).
 - Antihypertensives and heart medications.
 - Anticholinergic medicines (e.g., atropine).
 - Medicines that stimulate the nervous system (e.g., medicines used to treat narcolepsy or medicines used to treat attention deficit disorder - ADD).
 - Antipsychotics.
 - Digoxin, quinidine.
 - Medicines to treat Parkinson's disease (e.g., selegiline and rasagiline).
 - Medicines to treat migraine (e.g., ergot alkaloids).
 - Antacids (e.g., kaolin and aluminum hydroxide).
 - Apraclonidine (a medicine for glaucoma).
 - Other sympathomimetics for treatment of a cough and cold (e.g., to reduce congestion).
 - Medicines to treat asthma.
 - Oxytocin.

- Medicines to treat allergies (antihistamines).
- Opiate antagonists (e.g., naloxone, naltrexone, buprenorphine).
- General anesthetics.
- Narcotic analgesics.
- Medicines to treat diarrhea (e.g., loperamide, kaolin).
- Medicines to treat nausea (e.g., domperidone, metoclopramide).
- Ciprofloxacin (an antibiotic).
- Cimetidine (for treatment of gastric ulcer).
- Antiviral medicines (e.g., ritonavir).

❗ Use of the medicine and food

The medicine should be taken with or after meals.

❗ Use of the medicine and alcohol consumption

Do not drink wines or alcohol beverages during the course of treatment with the medicine.

❗ Pregnancy and breastfeeding

Do not use the preparation if you are pregnant or breastfeeding.

❗ Driving and operating machinery

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

❗ The effect on your daily life

The medicine may sometimes cause insomnia. To prevent this, the last dose of the day should be taken several hours before bedtime.

❗ Important information about some of the ingredients of the medicine

The preparation contains 3 g of sucrose and 2.5 mg of sodium per 5 ml of syrup.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The usual dose is generally:

Adults and children above 12 years of age: 10 ml, 3 times a day.

Do not exceed the recommended dose.

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

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.

Duration of treatment: If there is no improvement in your condition within 3 days, refer to the doctor.

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

If you forgot to take this medicine at the required time, take a dose as soon as you remember; however, under no circumstances should two doses be taken together!

Adhere to the treatment regimen recommended by the doctor.

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 further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Histafed Compound Linctus Syrup 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 the doctor immediately if the following effects occur:

- Signs of toxicity which include:** breathing difficulties, dizziness, extreme somnolence, confusion.
- Fever, swelling of the face, neck, tongue or throat, fainting, increased perspiration, blushing, severe rash, urticaria, itching or stomach pain (may indicate a severe allergic reaction).
- Eyes: blurred vision, double vision or pupil constriction (“pinpoint pupils”).
- Urinary system: difficulty/pain in passing urine, urine retention.
- Nervous system: weakness, tiredness, vertigo, seizures, increased intracranial pressure (painful eyes, vision disturbances, headache in the area between the eyes), headache, tolerance to the medicine (the medicine is having a decreased effect).
- Psychiatric: mood changes, depression, hallucinations, irritability, restlessness, nightmares, excitation, anxiety.
- Heart: heart rhythm disturbances, palpitations or irregular heartbeats, drop in blood pressure, drop in blood pressure in changing from a lying to a standing position, hypertension.
- Other: muscle stiffness, decreased libido, breathing difficulty, low body temperature, tremor, sleep disturbances, nausea or vomiting, dry mouth.

Additional side effects:

Feeling feverish, dizziness, fast heartbeat, constipation, glaucoma (increased intraocular pressure), vascular disturbances (such as a feeling of cold in the hands and legs), drowsiness, dryness in the nose and throat.

Side effects and drug interactions in children:

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

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept 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 the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and the bottle. The expiry date refers to the last day of that month.
- Store in a cool dark place, below 25°C.
- After first opening of the bottle, the medicine can be used for up to 6 months.

6. FURTHER INFORMATION

- In addition to the active ingredients, the preparation also contains the following inactive ingredients: Purified water, sucrose, glycerol, strawberry flavor, saccharin sodium, methyl hydroxybenzoate sodium, citric acid anhydrous, propyl hydroxybenzoate sodium.
- Each 5 ml contains 3 g of sucrose and 2.5 mg of sodium.
- What does the medicine look like and what are the contents of the package?** Each package contains a bottle with 115 ml of syrup and a measuring cup.
- Manufacturer and license holder:** Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- This leaflet was checked and approved by the Ministry of Health in July 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 027.93.21823.00

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