

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

This medicine is dispensed without a doctor's prescription

## **Histafed**

Film-coated tablets

### **Active ingredients**

**Histafed:** Each film-coated tablet contains:

2.5 mg triprolidine hydrochloride

60 mg pseudoephedrine hydrochloride

**Histafed syrup:** Every 5 ml contain:

1.25 mg triprolidine hydrochloride

30 mg pseudoephedrine hydrochloride

Inactive ingredients and allergens in this medicine: see section 2 under '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, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about the dosage in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve within 5 days.

### **1. What is this medicine intended for?**

For the symptomatic relief of congestion as in cases of rhinitis and allergic conditions.

### **Therapeutic group:**

Pseudoephedrine - alpha agonist, a decongestant that relieves nasal and sinus congestion

Triprolidine - H<sub>1</sub> antihistamine that helps stop sneezing, runny nose and watery eyes

### **2. Before using this medicine**

#### **Do not use this medicine:**

- If you or your child are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (see section 6).
- If you or your child have high blood pressure or heart disease or blood vessel disease, or if you or your child have a history of stroke.
- If you or your child are taking beta blockers (used to treat high blood pressure).
- If you or your child are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you or your child are taking other cough and cold medicines.
- If you or your child have lung disease or breathing difficulties.
- If you or your child have diabetes.
- If you or your child have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- If you or your child have an overactive thyroid gland.
- If you or your child have glaucoma (increased pressure in the eye).
- If you or your child have pheochromocytoma (rare tumour on the adrenal gland)

## **Histafed Syrup**

which affects your heart rate and blood pressure).

- In babies under the age of one year.

### Special warnings about using this medicine

#### Before using Histafed/Histafed Syrup, tell your doctor if:

- You or your child have **kidney** problems or **severe liver problems**.
- You or your child are susceptible to **glaucoma** (increased pressure in the eye).
- You or your child have **blocked arteries** or **veins** (occlusive vascular disease).
- You or your child are being treated for a **thyroid disorder**.
- You or your child have difficulty with passing water or needing to pass water often (for example, due to prostate problems, or infection/inflammation of the bladder or urinary tract).
- You or your child have **alcohol dependence**.
- You or your child have **epilepsy**.

If you or your child have the following reactions, stop taking the medicine and contact your doctor immediately:

- Generalised erythema with pustules associated with fever (see section 4).
- Sudden abdominal pain or rectal bleeding may occur with Histafed/Histafed Syrup due to inflammation of the colon (ischaemic colitis). If these gastro-intestinal symptoms develop, stop using Histafed/Histafed Syrup, and contact your doctor or seek medical attention immediately (see section 4).
- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Histafed/Histafed Syrup immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS. The symptoms are severe headaches with a sudden onset, feeling sick, vomiting, confusion, seizures or changes in vision.
- Reduction of blood flow to the optic nerve may occur when taking Histafed/Histafed Syrup. If sudden loss of vision develops, stop using the medicine and contact your doctor or seek medical attention immediately (see section 4).

**Anti-doping tests:** This medicine contains pseudoephedrine hydrochloride, which may produce positive results in anti-doping tests.

### Children and adolescents

This medicine is not intended for babies under the age of one year and is not recommended under the age of 6.

Children aged 1–6 years can be given this medicine only with a prescription.

Children under the age of 12 should be given this medicine in the syrup form.

Do not use this medicine to calm a child (sedation).

### Interactions with other medicines

**If you or your child are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.**

Particularly if you or your child are taking:

- Sedatives (drugs used to treat **anxiety and tension**).
- Antihypertensives (drugs used to treat **high blood pressure**, such as bretylium, betanidine, guanethidine, reserpine, debrisoquine, methyldopa, adrenergic neurone blockers) and diuretics.
- Stimulants or appetite suppressants and drugs used to treat **congestion and asthma** (sympathomimetic drugs).
- Tricyclic antidepressants (used to treat **mood disorders**).
- Moclobemide (used to treat **mood disorders**).

- Cardiac glycosides (drugs used to control **heart rhythms** or **heart contractions** e.g. digoxin).
- Ergot alkaloids (drugs used to treat **migraine**, such as ergotamine and methysergide).
- Oxytocin (drug used **to induce labour** – help contractions).
- Anticholinergic drugs (drugs used to treat **cramps** or **spasms** such as atropine).
- Hypnotics (**sleeping tablets**, including barbiturates).
- Opioid analgesics (drugs used to **relieve pain**, e.g. codeine, tramadol, morphine).
- Antipsychotics (used to treat **mood disorders**).
- Thyroid hormones.

If you are not sure about the medicine you or your child are taking, show the bottle or pack to your pharmacist.

If any of these points applies to you or your child now or in the past, contact your doctor or pharmacist.

### **Using this medicine and food**

Histafed/Histafed Syrup can be taken with or without food. Take it with food or milk in case of stomach discomfort.

### **Using this medicine and alcohol consumption**

Do not drink alcoholic beverages while taking this medicine.

### **Pregnancy and breast-feeding**

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.

### **Driving and using machines**

This medicine may cause dizziness, drowsiness, reduce alertness and impair hearing; if you experience these effects, do not drive or operate machinery.

Exercise caution when driving, operating dangerous machines and in any activity that requires alertness. Caution children against riding a bicycle, playing near a road and similar activities.

### **Important information about some of this medicine's ingredients**

**Histafed Syrup contains sucrose, methyl hydroxybenzoate sodium, propyl hydroxybenzoate sodium.**

**Sucrose** – If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking this medicine. This syrup may also harm the teeth if used for two or more weeks.

**Methyl hydroxybenzoate sodium (E219) and propyl hydroxybenzoate sodium** may cause allergic reactions; this may be a late reaction.

**Sodium** – This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially sodium-free.

### **3. How to use this medicine?**

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

The recommended dose unless otherwise instructed by your doctor:

#### ***Tablets:***

#### ***Adults and children over 12 years of age:***

1 tablet every 4-6 hours. Do not take more than 4 tablets in 24 hours.

Swallow the tablets with some water.

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

#### ***Children from the age 1 to 12 years:***

Give this medicine in the syrup form.

**Syrup:**

Adults and children over 12:

10 ml every 4–6 hours. Do not give more than 4 doses (40 ml) in 24 hours.

Children aged 6–12 years:

5 ml every 6–8 hours. Do not give more than 4 doses (20 ml) in 24 hours.

Children aged 1 to 6 years:

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

**This medicine is not intended for babies under the age of 1 year.**

**Note:**

To measure the right amount of the medicine, use the measuring cup that comes with the package. In children between the ages of 1 and 6, the dosage will be determined according to the doctor's instructions; Follow the pharmacist's recommendation to choose an appropriate measuring device. Do not use a household spoon to measure the amount of the medicine. Household spoons vary in size, and you may not get the correct amount of medicine. Wash the measuring device after use.

To reduce insomnia take the last daily dose a few hours before sleep.

**Treatment duration:** If your signs of illness (symptoms) get worse or do not improve in 5 days, contact your doctor.

**Do not exceed the recommended dose.**

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

**If you forget to take this medicine at the scheduled time,** take a dose as soon as you remember; if it is almost time for your next dose, skip the dose and take the next dose at the usual time. Never take two doses together!

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

As with any medicine, using Histafed/Histafed Syrup may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

**If the following effects appear, stop using this medicine and seek immediate medical attention:**

- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis (AGEP)) may occur within the first 2 days of treatment with this medicine (see section 2).
- Sudden stomach pains, passing blood in stools or bleeding from back passage and diarrhoea.
- Symptoms that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures, changes in vision.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (severe allergic reaction).
- Feeling unusually tired, unexpected bruising or bleeding and greater tendency towards

- infections (such as colds) than normal.
- Allergic reaction, including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
- Hallucinations, paranoid delusions or fits.

**If the following effects appear, stop using this medicine and contact your doctor:**

- Restlessness or sleep disturbances.
- A fast, slow or irregular heartbeat or an increased awareness of your heartbeat (palpitations).
- Trouble passing water (especially men with prostate problems).
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy).

**Additional side effects**

**Very common side effects** – effects that occur in more than one in ten users

- Headache

**Common side effects** – effects that occur in up to one in ten users

- Difficulty sleeping, nervousness, dizziness or feeling jittery
- Drowsiness
- Blurred vision
- Thickened mucus, dry mouth, nausea or an upset stomach.

**Rare side effects** – effects that occur in up to one in 1,000 users

- Confusion or depression
- Tremor, shakiness or slurred speech
- Low blood pressure.

**Side effects of unknown frequency** (the frequency of these effects has not been established yet)

- Stroke
- Heart attack/reduced blood flow to the heart which can cause discomfort or pain in the chest, neck, back, jaw, shoulders or arms (known as angina)
- Agitation, anxiety, irritability or feelings of extreme happiness
- Tingling or numbness of the hands or feet (pins and needles)
- High blood pressure
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis)
- Nosebleeds, dry nose or dry throat
- Vomiting or stomach discomfort
- Pain when passing urine
- Feeling tired
- Very high fever
- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

**If you or your child experience any side effect, if any side effect gets worse, or if you or your child experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>.

Side effects may also be reported to [safety@trima.co.il](mailto: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 the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

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

**Storage conditions:**

- Tablets: Store in a cool dry place, below 25°C.
  - Syrup: Store in a cool, dark place, below 25°C.
- Use the syrup within 6 months of first opening the bottle.

Do not throw away the medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help protect the environment.

**6. Additional information**

**In addition to the active ingredients, these medicines also contain the following inactive ingredients:**

**Histafed:**

dicalcium phosphate dihydrate, microcrystalline cellulose, maize starch, povidone, magnesium stearate, colloidal silicon dioxide, pregelatinized starch, Opadry OY 2857 red (hypromellose 5 cP, erythrosine aluminium lake, polyethylene glycol, quinoline yellow aluminium lake, titanium dioxide).

**Histafed Syrup:**

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

**What the medicine looks like and contents of the pack:**

Histafed: Packs contain 10, 20, or 30 red, biconvex, film-coated tablets in blister trays.

Histafed Syrup: child-resistant pack. A glass bottle with 115 ml colourless to pale yellow syrup.

**Registration holder and manufacturer's name and address:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Revised in June 2024.

**Registration numbers of the medicine in the Ministry of Health's National Drug Registry:**

Histafed: 027 94 21825 00

Histafed Syrup: 107 14 21824 00