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Histafed Expectorant Syrup

Active ingredients
Each 5 ml contains:
guaiphenesin 100 mg
pseudoephedrine HCl 30 mg
triprolidine HCl 1.25 mg

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?
An expectorant syrup and decongestant of the upper respiratory tract with anti-allergic action.
This medicine is for use in adults and children from the age of two years.

Therapeutic group:
Guaifenesin - expectorant
Pseudoephedrine - alpha agonist
Triprolidine - H₁ antihistamine

Histafed Expectorant Syrup is a medicine which is used to relieve the symptoms of colds and allergies including sneezing, runny nose, watery eyes, nasal congestion and blocked sinuses. The syrup contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion, triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes and guaifenesin which is an expectorant.

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) or to other decongestants.
- If you or your child have **high blood pressure** or heart disease or blood vessel disease, including poor circulation in the hands or feet.
- 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 problems**.
- If you or your child have **diabetes**.
- If you or your child have **severe kidney problems**.
- 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 **difficulty in passing water or need to pass water often** (for example, due to prostate problems, or infection or inflammation of the bladder or urinary tract).
- If you or your child have **pheochromocytoma** (rare tumour which affects your heart rate and blood pressure).
- If you are **pregnant or breast-feeding**.
- In babies under the age of two years.

Special warnings about using this medicine
Before using Histafed Expectorant Syrup, tell your doctor if:

- You or your child have **kidney 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 **prostate problems** (difficulty with passing water or needing to pass water often).
- You or your child have **alcohol dependence**.
- You or your child have **epilepsy**.
- You or your child have a long-term cough or asthma (do not take this medicine in case of wheezing or in case of an asthma attack).
- You or your child have a fever, rash or constant headaches.
- You or your child are scheduled for surgery.

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 Expectorant Syrup due to inflammation of the colon (ischaemic colitis). If these gastro-intestinal symptoms develop, stop using Histafed Expectorant Syrup, and contact your doctor or seek medical attention immediately (see section 4).
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.

- Reduction of blood flow to the optic nerve may occur when taking Histafed Expectorant Syrup. If sudden loss of vision develops, stop use of Histafed Expectorant Syrup and contact your doctor or seek medical attention immediately (see section 4).

Additional warnings
• The decongestant effect of this medicine may be reduced if it is in use for a long time.

- This medicine may interfere with some results of urine tests. If you or your child are scheduled to have any urine tests, tell the doctor or medical staff that you or your child are taking this medicine.
- **Anti-doping tests:** This medicine contains pseudoephedrine hydrochloride, which may produce positive results in anti-doping tests.

Children and adolescents
Use in children from the age of 2 to 6 is by doctor's prescription only.

This medicine is not intended for babies under the age of 2.

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 brelivium, betanidine, guanethidine, reserpine, debrisoquine, methyl dopa, 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 and stop bleeding after the birth**).
 - 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.

Using this medicine and food
Take this medicine with food or milk to reduce stomach discomfort.

Using this medicine and alcohol consumption
Do not drink alcoholic beverages while taking this medicine.

Pregnancy and breast-feeding
Do not take this medicine while pregnant or 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; 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 Expectorant 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.
Methyl hydroxybenzoate sodium 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:

Adults and children from 12 years of age: 10 ml every 4-6 hours, up to four times a day.

Children from the ages of 6 to 12: 5 ml every 6-8 hours, up to four times a day.
Use in children from the age of 2 to 6 is by doctor's prescription only.

This medicine is not intended for babies under the age of 2.

Attention: Be sure to measure the dose in the special measuring cup or measuring spoon.

Do not exceed the recommended dose.

Directions for use
Take this medicine with food or milk to reduce stomach discomfort. Take the last daily dose a few hours before sleep to prevent insomnia.

If you have accidentally taken a higher dose
If someone 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/give the medicine at the scheduled time
If you forget to take/give a dose of the medicine, take/give the next dose at the required time as long as the last dose was taken at least 4 hours ago. Do not take a double dose.

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 Expectorant 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.
- Severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (severe allergic reaction).
- Allergic reaction, including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.
- Hallucinations, paranoid delusions or fits.
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). The frequency of this effect is unknown.
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy). The frequency of this effect is unknown.

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).

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
- Vomiting or stomach discomfort
- Pain when passing urine
- Feeling tired
- Very high fever

- Dry mouth, thirst
- Feeling excited
- Muscle weakness, sweating
- Return of congestion, if the medicine has been used for a long time.

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), 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

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:
Store below 25°C. Store in the original package to protect from light. Use the medicine within 6 months of first opening and no later than the expiry date.

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, this medicine also contains: Sucrose, glycerol, strawberry flavor, saccharine sodium, methyl hydroxybenzoate sodium, propyl hydroxybenzoate sodium, citric acid anhydrous and purified water.

What the medicine looks like and contents of the pack:
Histafed Expectorant Syrup is a colourless to yellow liquid in a glass bottle. The bottle contains 115 ml of liquid.
The bottle is child resistant.

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

Revised in October 2023 according to Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 050-31-26252-00