

The format of this leaflet was determined by the Ministry of Health and its content was examined and approved by the Ministry.

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
This medicine is dispensed without a doctor's prescription

Histadex Syrup

Composition and quantity of active ingredients:

Each 5 ml contain the following active ingredients:

Dexchlorpheniramine maleate 1 mg

Pseudoephedrine HCL 25 mg

For the list of inactive ingredients of this medicine, see section 6 – "Additional information".

Read this leaflet carefully in its entirety before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to a doctor or pharmacist.

This medicine is not intended for children below the age of 6 years old.

You should use it correctly. Consult the pharmacist if you need additional information. Refer to a doctor if the disease symptoms worsen or do not improve.

1. What is the medicine intended for?

For relief of congestion in the airways caused by allergy.

Therapeutic group and medical action:

- Dexchlorpheniramine maleate – an antihistamine (counteracts the effects of histamines).
- Pseudoephedrine HCL – an alpha agonist decongestant.
Pseudoephedrine HCL causes vasoconstriction, thus reducing congestion in the airways.

2. Before using this medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients, or to any other antihistamine, or to any of the additional ingredients contained in the medicine. For the list of inactive ingredients see section 6 – "Additional information".
- You are pregnant or breastfeeding.
- You are currently being treated with a monoamine oxidase inhibitor (MAOI) medicine, or have stopped treatment with such a medicine within the past 14 days.
- You are using a beta blocker medicine (for the treatment of hypertension) or other medicines for cough and cold.
- You suffer from high blood pressure, heart disease, narrow angle glaucoma, or symptomatic prostate enlargement.
- You suffer from severe renal failure, diabetes, hyperthyroidism or pheochromocytoma.
- Do not use the medicine in children below the age of 6 years old.

Special warnings regarding the use of this medicine:

Before beginning treatment with Histadex, tell your doctor if:

- You suffer or have previously suffered from impaired prostate function.
- You suffer or have previously suffered from impaired urinary bladder function.
- You suffer or have previously suffered from moderate kidney disease, or from severe liver disease.

You must inform the doctor about taking this medicine if you go to a hospital emergency room, because this medicine may interfere with other medicines or anesthetic agents.

If you are sensitive to any food or medicine, you should inform the doctor before beginning treatment with this medicine.

If you are taking, or if you have recently taken other medicines, including non-prescription medicines or food supplements, inform your doctor or pharmacist!

Do not use together with:

- Monoamine oxidase inhibitor (MAOI) medicines (antidepressants), or within 14 days after having stopped using them.
- Beta receptor blockers or other medicines for the treatment of nasal congestion (including nasal spray).

Pay special attention to medicines of the following classes:

- Central nervous system stimulants (such as amphetamines).
- Appetite suppressants.
- Antidepressants.
- Anti-hypertensive medicines.
- Medicines for the treatment of heart disease, such as beta blockers, digoxin, quinidine.
- Medicines for the treatment of cough and cold.
- Medicines for the treatment of mental disease.
- Medicines for the treatment of Parkinson's disease, such as selegiline.
- Medicines for the treatment of glaucoma, such as apraclonidine.
- Antacids such as aluminum hydroxide, kaolin.
- Antibiotics such as furazolidone.
- Moclobemide (for the treatment of mood disorders).
- Ergot alkaloid medicines (for the treatment of migraine).
- Oxytocin.

Use of the medicine and alcohol consumption:

Refrain completely from consuming alcohol during treatment with Histadex.

Pregnancy and breastfeeding:

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

Driving and using machinery:

Use of this medicine may impair alertness, therefore it requires caution while driving a car, operating dangerous machinery, and in any activity requiring alertness.

Children should be cautioned against riding a bicycle, playing near a road, etc.

Important information about some of the medicine's ingredients:

Please note: This medicine contains **methylparaben** and **propylparaben**, which may cause allergic reactions (delayed reactions may occur). The medicine contains sorbitol and sucrose. If you have been told that you suffer from intolerance to certain sugars, consult your doctor before

using this medicine.

The medicine contains 194 mg alcohol in each 5 ml of syrup. This quantity may be harmful for people suffering from alcoholism.

This should also be taken into account in children and in high risk groups such as patients with liver disease or epilepsy.

3. How to use this medicine:

Check with the doctor or pharmacist if you are unsure.

Dosage: The standard dosage, unless otherwise instructed by a doctor:
Adults: 5-10 ml twice a day.

Children aged 6-12 years old: 5 ml once a day.

This medicine is not intended for infants or children below the age of 6 years old.

Do not exceed the recommended dose.

Please note: Measure the dose carefully using the enclosed measuring cup. Do not use a regular teaspoon to measure the dose. Teaspoons vary in size and you might not obtain the correct amount of medicine.

Use of the medicine and food: Take the medicine with food.

This medicine should be taken several hours before bedtime to avoid sleep disruption.

Maximum period of treatment: Do not use this medicine often or for a prolonged period of time without consulting a doctor.

If you forgot to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult a pharmacist or a doctor.

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

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

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

4. Side effects:

As with any medicine, the use of Histadex may cause side effects in some users. Do not be alarmed by the list of side effects; you may not experience any of them.

Stop the treatment and refer to a doctor immediately if the following symptoms appear:

- Allergic reaction; the symptoms may include: skin rash (which may be severe and include blistering or peeling of the skin), itching, difficulties breathing, fever, swelling of the mouth, face, lips, tongue or throat, abdominal pain.
- You suffer from allergic reaction to other medicines containing sympathomimetic agents (such as central nervous system stimulants and appetite suppressants, cold medications and medicines for asthma).
- You suffer from hallucinations and anxiety-induced (paranoid) delusions.

Stop the treatment and refer to a doctor if:

- You suffer from increased or irregular heart rate, palpitations, high blood pressure.
- Restlessness or sleep disorders.

Additional side effects:

Irritability, excitement, anxiety, nausea, vomiting, headache, difficulty urinating, glaucoma, tremor, dry mouth, reduced blood flow (cold hands and feet), mental diseases (rare).

If a side effect appears, if any of the side effects worsens or if you experience a side effect not mentioned in this leaflet, you should consult a doctor.

Side effects and drug interactions in children and infants:

Parents must inform the attending doctor about any side effect and any other medicine administered to the child!

See the side effects and drug interactions specified above.

Side effects can be reported to the Ministry of Health by clicking the link "Report of side effects due to medication" on the home page of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects.

5. How should this medicine be stored?

- Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach of children and/or infants, 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 that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Store in the original package. Do not store different medicines in the same package.

6. Additional information:

In addition to the active ingredients, each 5 ml of the medicine also contain the following inactive ingredients: sucrose 2g, sorbitol 70% 650 mg, glycerine, alcohol 95%, propylene glycol, methyl paraben, strawberry flavor, propylparaben, lemon oil, purified water.

What the medicine looks like and what the package contains: The medicine is a clear colorless syrup. A measuring cup is enclosed in the package.

Medicine registration number: 631628042

Manufacturer and Registration Holder:

Vitamed Pharmaceutical Industries Ltd.

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