



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

SINUFED

10 Tablets/Syrup

Sinufed Tablets:

Pseudoephedrine hydrochloride 60 mg

Sinufed Syrup:

Each 5 ml contains:

Pseudoephedrine hydrochloride 30 mg
For inactive ingredients in the preparation – see section 6 "Further Information".

Read this package insert 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.

You must use the medicine in the correct manner. Consult the pharmacist if you need further information. Consult the doctor if signs of the illness (symptoms) worsen or if they do not improve after 7 days.

For children below 12 years of age, it is recommended that the medicine be taken in the syrup form. The syrup dosage form is not intended for infants under one year of age. For children over one year and under 6 years of age, a doctor should be consulted.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for symptomatic treatment of nasal congestion in cases of acute rhinitis and relief of eustachian tube congestion due to ear infection.

Therapeutic group Alpha-agonist.

2. BEFORE USING THE MEDICINE

❌ Do not use the medicine if:

- you are sensitive to the active ingredient or to any of the other ingredients the medicine contains (see section 6).
- Do not use in infants under one year of age.
- you are pregnant 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 suffer from heart diseases such as: ischemic heart disease, occlusive vascular disease or hypertension.
- you have diabetes.
- you suffer from severe kidney function impairment.
- you have a pheochromocytoma (a rare tumor of the adrenal glands).
- you have an overactive thyroid gland.
- you have glaucoma.
- you have an enlarged prostate gland.
- 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.

⚠️ Do not use this medicine without

consulting a doctor before beginning treatment if:

- you suffer from impaired liver or kidney function.
- you suffer from impaired function of the urinary bladder.
- you are about to undergo surgery, due to a possible reaction with anesthetics.
- you are sensitive to any food or medicine.

⚠️ If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially tell the doctor or pharmacist if you are taking:

- appetite suppressants
- medicines that stimulate the nervous system (e.g., medicines used to treat narcolepsy or medicines used to treat attention deficit disorder ADD)
- medicines to lower blood pressure (e.g., beta blockers)
- antipsychotics
- medicines for treatment of depression (e.g., monoamine oxidase inhibitors MAOI)
- digoxin, quinidine
- medicines to treat Parkinson's disease (selegiline and rasagiline)
- medicines to treat migraine (ergot alkaloids)
- antacids (kaolin and aluminium hydroxide)
- furazolidone (antibiotic)
- apraclonidine (medicine for glaucoma)
- other sympathomimetics (e.g., to reduce congestion)
- oxytocin

⚠️ Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not use the preparation.

⚠️ Sinufed and your daily life

Sometimes Sinufed may 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 syrup

The preparation contains 3 grams of sucrose and 2.5 mg of sodium in every 5 ml syrup.

3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure. The usual dosage is generally:

Tablets:

Adults and children above 12 years of age: One tablet every 6 hours. Do not take more than 4 tablets within 24 hours.

Swallow the tablets with a small amount of water. The tablets may be halved. There is no information regarding crushing/chewing.

Children below 12 years of age:

It is recommended that the medicine be taken in the syrup dosage form.

Syrup:

Adults and children above 12 years of age:

10 ml every 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 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 infants under one year of age.

Attention:

1. With liquid medications, you must use a measuring cup, syringe or dropper meant for measuring the correct amount of medicine. **The enclosed measuring cup is not suitable for measuring the dose for children under 2 years of age.** 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.

2. Child-proof caps have significantly reduced the number of cases of medicine-induced poisoning each year. However, if you find it difficult to open the container, you can ask the pharmacist to remove the safety mechanism of the cap and make it a regular easy-to-open cap.

Adhere to the treatment regimen recommended by the doctor.

Duration of treatment: If there is no improvement in your condition within 7 days, contact the doctor.

Do not exceed the recommended dose.

If you accidentally took an overdose or if a child accidentally swallowed the medicine, refer to the doctor immediately or proceed to a hospital emergency room and bring the package of the medicine with you. The signs you may experience are: Agitation, palpitations, elevated blood pressure, difficulty passing urine, nausea/vomiting, increased thirst or seizures.

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!

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 use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Sinufed may cause side effects in some users. Do not be alarmed when 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:

- Breathing difficulties, fever, swelling of the face, neck, tongue or throat, severe rash, itching or stomach pain (may indicate a severe allergic reaction).
- Heart rhythm disturbances, palpitations, high blood pressure, anxiety, tremor, urine retention (in men), rash.
- Hallucinations and paranoia (rare), reported especially in children.

Refer to the doctor immediately if the following effects occur:

Nervousness, agitation, insomnia, nausea or vomiting, headache, dry mouth.

Additional side effects:

Glaucoma (increased intraocular pressure), blood circulation problems (such as feeling a cold sensation in the hands and feet).

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 any of the side effects worsen, or if you experience a side effect not mentioned in the leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept 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 (exp. date) that appears on the package/blister/label. The expiry date refers to the last day of that month.
- Store in a dark and cool place, below 25°C.
- Syrup: after first opening the bottle, the medicine can be used for up to 6 months.

6. FURTHER INFORMATION

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

Sinufed Tablets: Calcium hydrogen phosphate, microcrystalline cellulose, povidone, carmellose sodium LS, colloidal silicon dioxide, magnesium stearate, titanium dioxide, HPMC 2910, PEG400, erythrosine aluminium lake, quinoline yellow aluminium lake.

Sinufed Syrup: Sucrose, glycerol, strawberry flavor, saccharin sodium, methyl hydroxybenzoate sodium, citric acid anhydrous, propyl hydroxybenzoate sodium, purified water.

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?

Sinufed Tablets: The package contains 10 round red-coated tablets.

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

• **Manufacturer:** Trima Israel Pharmaceutical Products Ltd., Maabarot 4023000, Israel.

• This leaflet was checked and approved by the Ministry of Health in: January 2014.

• Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Sinufed Tablets: 030.06.25464.00
Sinufed Syrup: 118.91.29978.00

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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