

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

This medicine is dispensed without a doctor's prescription

**Sinufed Tablets**

**Active ingredient**

Each tablet contains 60 mg  
pseudoephedrine hydrochloride

**Sinufed Syrup**

**Active ingredient**

Each 5 ml contain 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.

Use this medicine according to the instructions in the section about 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 after 5 days.

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

For symptomatic treatment of nasal congestion and relief of eustachian tube congestion.

**Therapeutic group:** sympathomimetic.

The active ingredient pseudoephedrine hydrochloride is a decongestant that relieves nasal and sinus congestion.

**2. Before using this medicine**

**Do not use this medicine:**

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- If you have high blood pressure, heart or blood vessel disease or a history of stroke.
- If you have diabetes.
- If you have a phaeochromocytoma (a rare adrenal gland tumour that affects the heart rate and blood pressure).
- If you have an overactive thyroid gland.
- If you have glaucoma (increased pressure in the eye).
- If you have severe acute (sudden) or severe chronic (long-term) kidney disease or kidney failure.
- If you are taking beta blockers (used to treat high blood pressure).
- If you are taking, or have taken in the last two weeks, medicines for depression known as Monoamine Oxidase Inhibitors (MAOIs) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you are taking stimulants or appetite suppressants or medicines used to treat congestion and asthma (sympathomimetic medicines).

- If you are taking any other cough and cold medicines.
- In infants under 1 year of age.

If any of these apply to you, consult your doctor or pharmacist without using Sinufed.

### **Special warnings about using this medicine**

#### **Before using Sinufed, tell your doctor:**

- If you have kidney problems or severe liver problems.
- If you have blocked arteries or veins (occlusive vascular disease).
- If you are being treated for a thyroid disorder.
- If you have difficulty urinating and/or an enlarged prostate (which may cause you to urinate more often).

If any of these bullet points apply to you now or have applied to you in the past, consult your doctor or pharmacist.

### **Additional warnings**

#### **If you experience the following reactions, stop taking this medicine immediately and contact your doctor:**

- A feverish generalised erythema associated with pustules (see section 4).
- Sudden abdominal pain or rectal bleeding may occur with this medicine due to inflammation of the colon (ischaemic colitis). If you develop these gastrointestinal symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately (see section 4).
- Reduction of blood flow to the optic nerve may occur with this medicine. If you develop sudden loss of vision, stop taking this medicine 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 Sinufed immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS. Symptoms are severe headaches with a sudden onset, feeling sick, vomiting, confusion, seizures or visual disturbances.

### **Children and adolescents**

The medicine is not intended for children under 1 year of age.

For children aged 1-6 years, the medicine is dispensed with a doctor's prescription only.

For children under 12 years of age, it is recommended to administer the medicine in syrup dosage form.

### **Interactions with other medicines**

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

- Antihypertensives (used to treat high blood pressure, such as guanethidine, methyldopa, adrenergic neurone blockers and beta blockers, debrisoquine,

bretylium and betanidine).

- Tricyclic antidepressants (used to treat mood disorders).
- Anticholinergic medicines (used to treat cramps or spasms).
- Moclobemide (used to treat mood disorders).
- Cardiac glycosides (used to control heart rhythms or contractions, such as digoxin).
- Ergot alkaloids (used to treat migraine, such as ergotamine and methysergide).
- Oxytocin (used to help in contractions during childbirth).

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

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

Sinufed syrup contains sucrose. If you have been told by your doctor that you have an intolerance to certain sugars, inform your doctor before taking this medicine. Sucrose may cause damage to your teeth when used for 2 weeks or longer.

Sinufed syrup contains methyl hydroxybenzoate sodium (E219) and propyl hydroxybenzoate sodium, which may cause allergic reactions (possibly delayed).

Sinufed tablets and syrup contain less than 1 mmol (23 mg) sodium per dose, and are considered 'sodium-free'.

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

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. The recommended dosage is usually:

#### **Tablets:**

##### Adults and adolescents over 12 years of age:

One tablet every 6 hours. Do not take more than 4 tablets per day.

Swallow the tablets with some water. The tablets can be split. There is no information regarding crushing or chewing.

##### Children under 12 years of age:

It is recommended to administer the medicine in syrup dosage form.

#### **Syrup:**

##### Adults and adolescents over 12 years of age:

10 ml every 6 hours. Do not take more than 4 doses (40 ml) per day.

##### Children aged 6-12 years:

5 ml every 6 hours. Do not take more than 4 doses (20 ml) per day.

##### Children aged 1-6 years:

The dosage will be determined according to a doctor's instruction.

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

### **Do not exceed the recommended dose.**

Attention:

- For measuring the correct medicine amount, you must use the measuring cup enclosed in the package. For children aged 1 to 6 years, the dosage will

be determined according to the doctor's instruction. For choosing the right measuring device, ask a pharmacist for advice. Do not use a household teaspoon to measure the medicine amount. Household teaspoons differ in size, and you may not get the correct medicine amount. Wash the measuring device after use.

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

### **If you have accidentally taken a higher 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. The following symptoms may occur in case of an overdose: high blood sugar level (hyperglycaemia), low blood potassium level (hypokalaemia), insomnia; irritability, agitation, anxiety, restlessness, confusion, delirium, hallucinations, psychoses, fits, tremor, intracranial haemorrhage including intracerebral haemorrhage, drowsiness (in children), pupil dilation, palpitations, rapid heart rate (tachycardia), slow heart rate (bradycardia), irregular heart rate, myocardial infarction, hypertension, vomiting, blockage of blood flow to the intestine, acute kidney failure, difficulty urinating.

### **If you forget to take the medicine**

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 your doctor.

If the medicine is used according to a doctor's prescription, adhere to the treatment as recommended by your doctor.

**Do not take medicines in the dark! Check the label and 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 Sinufed 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 you experience any of the following, stop using the medicine and seek immediate medical help:**

- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders or arms), or heart attack.
- Stroke (weakness of the face, arms or legs, or speech problems).
- 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).
- Swelling of the face, lips, mouth, tongue or throat, which may cause difficulties in swallowing or breathing.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.

- Hallucinations or paranoid delusions (seeing or hearing things that are not there, irrational thoughts or feelings).
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms may include sudden abdominal pain or rectal bleeding.
- Sudden loss or reduction of vision which may be caused by reduced blood flow to the optic nerve (ischaemic optic neuropathy).
- 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 or visual disturbances

**If you experience any of the following, stop using the medicine and contact your doctor:**

- Difficulty urinating (especially in men with prostate problems).

#### **Additional side effects**

Very common side effects - affect more than one in ten users:

- Headache

Common side effects - affect up to one in ten users:

- Difficulty sleeping, nervousness or dizziness
- Dry mouth or nausea

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

- Vomiting
- Anxiety, irritability, feeling jittery or feelings of extreme happiness
- Restlessness or sleep disturbances
- Fast or irregular heartbeat or increased awareness of heartbeats (palpitations).
- Pain during urination
- High blood pressure
- Drowsiness
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy)
- Pins and needles (paraesthesia) in fingers and toes
- Tremor
- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

**If you experience any side effect, if any side effect gets worse, or if you 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>  
You can also report by email 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. The expiry date refers to the last day of that month.

#### **Storage conditions:**

Store below 25°C.

Tablets: Protect from light. Store in a cool and dry place.

Syrup: Store in a cool and dark place.

Shelf life after opening the bottle: 6 months.

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

#### **6. Additional information**

##### **In addition to the active ingredient, this medicine also contains:**

##### Tablets

Calcium hydrogen phosphate, microcrystalline cellulose, povidone, carmellose sodium LS, colloidal silicon dioxide, magnesium stearate, HPMC, erythrosine aluminium lake, PEG, quinoline yellow aluminum lake, titanium dioxide.

##### Syrup

Sucrose, glycerol, strawberry flavour IFF 15.08.1059, saccharin sodium, methyl hydroxybenzoate sodium (E218), citric acid anhydrous, propyl hydroxybenzoate sodium, purified water.

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

Tablets: Round red-coated tablets in a pack containing 10 tablets in a blister.

Syrup: A colourless to yellowish liquid in a glass bottle containing 115 ml, closed with a child-resistant cap. The pack also contains a measuring cup.

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

Revised in January 2025.

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

Sinufed Tablets: 030-06-25464-00

Sinufed Syrup: 118-91-29978-00