

## KALSINUS TABLETS 60 mg 10 tablets package

The active ingredient and its quantity:

Each tablet contains: Pseudoephedrine hydrochloride 60 mg

For a list of inactive ingredients, please see section 6.

**Read this leaflet carefully in its entirety before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is not intended for children under the age of 12 years (below this age, refer to a doctor). Swallow it properly. Consult a pharmacist if you need further information. Refer to a doctor if the signs of the disease (symptoms) worsen or do not improve after 7 days.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

- The medicine is intended for symptomatic treatment of nasal congestion in acute rhinitis and for 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 breastfeeding.
- you are sensitive (allergic) to the active ingredient (pseudoephedrine hydrochloride) or to any of the other ingredients contained in the medicine.
- you are under concomitant treatment with medicines from the monoamine oxidase inhibitors (MAOIs) group (for treatment of depression), or within 14 days of discontinuing treatment with them.

#### Special warnings regarding use of the medicine:

- Consult a doctor if you are due to undergo an operation, due to possible interaction with the anesthetics.
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.

#### ☒ Before treatment with Kalsinus, tell the doctor:

- if you are pregnant.
- if you are suffering, or have suffered in the past, from impaired function of: the eyes (e.g., glaucoma), heart and/or blood vessels (e.g., high blood pressure), thyroid, prostate gland, from diabetes.
- before giving this medicine to the elderly, as they may be sensitive to anticongestants.

**☒ If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, inform the doctor or pharmacist.** It is especially important to inform the doctor or pharmacist if you are taking:

- Antidepressants
- Antihypertensives
- Diuretics
- MAO inhibitors
- Preparations containing digitalis glycosides
- Levodopa
- Nitrates
- Thyroid hormones

#### ☒ Pregnancy and breastfeeding:

If you are pregnant, consult a doctor or pharmacist before taking medicines.

Do not use this medicine if you are breastfeeding.

### 3. HOW SHOULD YOU USE THE MEDICINE?

- Check with the doctor or pharmacist if you are not sure.

#### The recommended dosage is usually:

Adults above the age of 12: One tablet every 6 hours.

Do not take more than 4 tablets within 24 hours.

#### Do not exceed the recommended dose.

The preparation can sometimes cause insomnia. In order to avoid this, take the last dose of the day a few hours before going to sleep.

Swallow the tablets with a little water.

The tablets can be halved or crushed immediately before swallowing. Do not store halved or crushed tablets.

If there is no improvement in your condition within 7 days, refer to a doctor.

**If you took an overdose** or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take this medicine** at the scheduled time, take a dose as soon as you remember, but never take a double dose.

Adhere to the treatment recommended by the doctor.

- 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 this medicine, consult the doctor or pharmacist.

### 4. SIDE EFFECTS:

As with any medicine, use of Kalsinus may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

#### Discontinue use of the medicine and refer to a doctor immediately if:

- you suffer from nervousness, restlessness, insomnia, breathing problems, nausea or vomiting (rare).

If any of the side effects worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from a doctor!
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature that exceeds 25°C.

### 6. FURTHER INFORMATION:

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

Calcium hydrogen phosphate, powdered cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, erythrosine Al.

Each tablet contains less than 3 mg sodium.

#### What the medicine looks like and the contents of the package:

Round, pink tablets with a scoreline.

The tablets come in aluminium blister trays in packages of 10 tablets.

#### License holder and manufacturer and address:

Sam-On Ltd., 25 Haavoda St., Bat-Yam.

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

148 21 33484 00

This leaflet was checked and approved by the Ministry of Health in July 2013.