

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

Read this package insert carefully in its entirety before using this medicine

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

BRONCHOLATE SYRUP

Composition: Each 5 ml contains:

Diphenhydramine HCl 10 mg

Pseudoephedrine HCl 20 mg

Inactive ingredients: Sugar, Sorbitol, Alcohol, Potassium Citrate, Citric Acid, Sodium Benzoate, Sodium Saccharine, Cherry Flavour, Menthol, Ponceau 4R, Purified Water.

Therapeutic group and action:

Pseudoephedrine: Sympathomimetic decongestant.

Diphenhydramine: Anti-histamine active against allergies.

Indications: Symptomatic relief of nasal congestion caused by influenza, hay fever and other allergies in the upper respiratory tract.
Nasal congestion associated with sinusitis.

Symptomatic relief of eustachian tube congestion in ear infection.

Symptomatic relief of cough, sneezing and cold (accompanied or not accompanied by nausea).

Symptomatic relief of rhinitis caused by allergy or infection.

When should the preparation not be used?

Do not use this medicine if you are breast-feeding.

Do not use this medicine if you are sensitive to any of its ingredients.

Do not use this medicine concomitantly with a monoamine oxidase inhibitor (MAOI) antidepressant or within 14 days following cessation of treatment with MAOI.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant in the first/third trimester. If you are suffering, or have suffered in the past, from impaired function of the respiratory system (e.g. asthma), the heart and/or vascular system (e.g. hypertension), the eyes (e.g. glaucoma), the liver, the kidney/urinary tract, the digestive system (e.g. ulcer), the thyroid gland, the prostate gland, diabetes. Elderly patients should also consult a doctor before commencing treatment with this medicine since they may be sensitive to decongestant preparations.

How will this medicine affect your daily life?

Use of this medicine may impair alertness and therefore caution should be exercised when engaging in activities such as driving a vehicle, operating dangerous machinery and in any other activity which requires alertness. Children should be cautioned against engaging in activities such as bicycle riding, playing near roads and the like.

Do not drink wines or alcoholic beverages while under treatment with this medicine.

Warnings: You must inform your physician if you are about to undergo surgery because of possible interaction with the anesthetic.

Use of this medicine may cause blurring of vision.

Do not use this medicine frequently, or for a long period, without consulting

a doctor. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Discontinue treatment with this medicine 4 days before undergoing skin testing procedures.

Drug interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: drugs affecting the central nervous system (e.g. sedatives, hypnotics, drugs for parkinsonism, epilepsy), antidepressants of the MAOI group, antihypertensives and diuretics, other cough and cold medicines.

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: dryness of mouth, drowsiness, palpitations.

Effects that require special attention: Nervousness, restlessness (rare): stop treatment and refer to the doctor immediately! Insomnia (rare): stop treatment and refer to the doctor immediately! Nausea or vomiting (rare): stop treatment and refer to the doctor immediately! In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

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 being taken by the child!

Unless otherwise directed by your doctor the recommended dosage is:

Adults: 15 ml, 3 times daily.

Children over 6 years of age: 5 ml, 1-3 times daily.

Use in children 1-6 years of age requires a doctor's prescription.

Do not exceed the recommended dosage.

This medicine is not intended for administration to children under 1 year of age.

If there is no improvement in your condition within 5 days, refer to your doctor.

Attention: Take care to measure the dose using a measuring spoon, special measuring cup, dropper, etc.

Directions for use: Swallow the medicine with a large amount of water, a little food or drink in the case of heartburn.

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor!
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: In a cool and dark place. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

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Manufacturer: Sam-On Ltd., 25 Haavoda Street, Bat-Yam.