

**PATIENT PACKAGE INSERT ACCORDING TO 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  
which also checked and approved its content

## **BRONCHOLATE PLUS** Tablets

**Composition:** Each tablet contains:

Paracetamol 400 mg  
Pseudoephedrine HCl 30 mg  
Diphenhydramine HCl 20 mg

Inactive ingredients: Sodium Starch Glycolate, Colloidal Anhydrous Silica, Quinoline Yellow AI, Microcrystalline Cellulose, Magnesium Stearate, Purified Water, Sepifilm LP 770.

**Therapeutic activity:** Symptomatic relief of cold, cough and nasal congestion accompanied by fever and pain. Adjunctive therapy for middle ear congestion.

### **When not to use this medicine?**

Do not use this medicine if you are breast-feeding.  
Do not use if you are hypersensitive to one of the components of the medicine. Do not use this medicine if you are taking monoamine oxidase (MAO) inhibitors, or within two weeks of finishing treatment with them.

**Do not start to use this medicine without first consulting your physician:** If you are pregnant, if you are suffering, or have suffered in the past from impaired function of: the respiratory system (such as asthma), the heart and/or blood vessels, eyes (such as glaucoma), the liver, the kidneys/urinary tract, the digestive system (such as ulcer), the thyroid gland, the prostate gland, diabetes, hypertension, mental illness.

### **How might this medicine affect your daily life?**

Use of this medicine may impair alertness. Caution should be exercised when driving a vehicle, operating dangerous machinery or performing any other activity that requires special vigilance. Children should be cautioned against riding a bicycle, playing near roads and the like.

**Warnings:** Paracetamol may cause damage to the liver in the following cases: when administered at a higher dosage than the recommended one, when administered for extended periods, when consuming alcoholic beverages during the treatment period, when taking additional medicines that affect the liver. Do not take additional fever-reducing and pain-relieving medicines, or medicines for common cold without consulting a doctor or a pharmacist, in order to prevent paracetamol overdose/toxicity. If you are sensitive to any foods or drugs inform your physician before starting treatment. Before undergoing any surgery (including dental surgery) or emergency treatment, inform your physician that you are taking this medicine. Discontinue treatment with this medicine 4 days before undergoing skin testing procedures. Do not use this medicine frequently without consulting a doctor.

**Drug interactions:** If you are taking another medicine concomitantly or if you have just finished treatment with another medicine, inform your

physician in order to prevent hazards or inefficacy arising from drug interactions. In particular, the following therapeutic groups may interact with your medicine: drugs that affect the central nervous system (such as sedatives, hypnotics, drugs for Parkinson's disease, epilepsy), anticoagulants, antidepressants such as monoamine oxidase inhibitors (See "When not to use this medicine?"), antihypertensives, non prescription medicines containing paracetamol, other cough and cold medicines, drugs affecting the liver (such as barbiturates and anticonvulsants), prolonged use of arthritis drugs, drugs for heart diseases (such as beta-adrenergic blockers or digitalis glycosides).

**Side effects:** In addition to the desired effect of the medicine, unwanted side effects may also appear, such as: dryness of mouth, drowsiness, vertigo, nervousness or restlessness, irritability.

**Side effects that require special attention:** Nausea, vomiting or stomach pain, rise in blood pressure: continue with the treatment and refer to your physician immediately! Difficulty or pain in urinating (rare): continue with the treatment and refer to your physician immediately! Bleeding, unusual tiredness or weakness (rare): continue with the treatment and refer to your physician immediately! Skin itching and rash (rare): continue with the treatment and refer to your physician immediately! If at any time you experience side effects that are not mentioned in this leaflet or if you feel a change in your general well-being, consult your physician immediately.

**Dosage:** Unless otherwise directed by the physician, the recommended dosage for adults is: 1-2 tablets 3 times daily.

Dosage according to physician's instructions only.

Do not exceed the recommended dosage.

If there is no improvement in your condition after 7 days treatment, consult your physician. If you forgot to take the medicine at the proper time, take the missed dose as soon as you remember, but on no account take two doses at the same time. The elderly are likely to be more susceptible to the side effects of this medicine.

**Directions for use:** Swallow the medicine with water. The tablet can be halved or crushed immediately before swallowing. Do not store halved or crushed tablets.

**Prevent poisoning!** This medicine, like all medicines, should be kept in a closed cupboard, out of the reach of children and/or infants in order to prevent poisoning. If you took an overdose, or if a child accidentally swallowed some of the medicine, go immediately to the emergency room of a hospital and bring with you any remaining medicine and the original packaging.

Do not induce vomiting without explicit instructions from the physician!

**Do not take any medicine in the dark!** Carefully check the label and dose each time you take the medicine. Wear your glasses if you need them.

**Storage:** Keep in a cool and dark place.

Even if stored according to the manufacturer's recommendations, all medicines have a limited shelf life. Please pay attention to the expiry date of the medicine. If you have any doubts, please consult the dispensing pharmacist. Do not store different medicines in the same container.

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**Manufacturer:** Sam-On Ltd., 25 Ha-avoda Street, Bat-Yam.