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

This medicine is dispensed with a doctor's prescription only

BRONCHOLATE FORTE SYRUP

The active ingredients and their quantities:

Each 5 mL contain:

Pseudoephedrine HCl 20 mg

Diphenhydramine HCl 10 mg

Codeine Phosphate 5 mg

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

Read this leaflet 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.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children under 12 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

- To relieve symptoms of cough accompanied by nasal congestion or Eustachian tube congestion due to ear infection.

Therapeutic group:

Pseudoephedrine - sympathomimetics, decongestant.

Diphenhydramine - antihistamines, against allergy.

Codeine - opiates, cough suppressant.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to any of the active ingredients (codeine, diphenhydramine or pseudoephedrine hydrochloride) or to any of the other ingredients of the medicine.
- You are pregnant or breastfeeding.
- You are suffering from respiratory depression.
- Do not use concomitantly with medicines from the monoamine oxidase inhibitors (MAOI) group (for treatment of depression), or within 14 days of discontinuing treatment with them.
- 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.
- You suffer from hyperthyroidism.
- You have glaucoma.
- You have an enlarged prostate gland.
- You are taking other medicines to treat congestion including nasal sprays.
- You are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma, are in the midst of an asthma attack, bronchitis, chronic pulmonary disease), heart failure due to chronic pulmonary disease, liver failure, head injury, intracranial pressure, obstruction of the intestine or bladder, gastric ulcer, alcoholism, diarrhea

due to poisoning or antibiotics.

- Do not use when you have chronic cough or chronic constipation.
- You have narrow-angle glaucoma.
- You have porphyria.
- This preparation is not intended for children under 12 years of age.
- Do not use in children between the ages of 12-18 years after a tonsillectomy or adenoidectomy performed to treat obstructive sleep apnea.
- You know that you produce a significant amount of morphine from a codeine dose (you belong to the ultra-rapid metabolizers group), as you are at increased risk of suffering from severe side effects upon use of codeine.

Do not use this medicine without consulting a doctor before starting treatment

If you are suffering or have suffered in the past, from the following conditions: Addison's disease, gall bladder disease, or gallstones, fits, epilepsy, weakness, muscle weakness (myasthenia gravis), low blood pressure, addiction to drugs or medicines, mental illness, urinary retention, tinnitus, impaired function of the nervous system.

Special warnings regarding use of the medicine:

- Naturally and rarely, in some people, codeine undergoes metabolism (breakdown) more rapidly than in most people. In these rare cases, high levels of metabolites may accumulate, which can cause severe side effects, such as: excessive drowsiness, confusion or shallow breathing. In such cases, the patient should be referred immediately for medical care. In most cases, it is impossible to know in advance whether a patient belongs to the group of people at risk for this effect.

- If you are about to undergo surgery of any sort (including dental), or emergency treatment, inform the doctor that you are taking this medicine.
- Prolonged use may cause dependence!
- Use of this medicine may cause blurring of vision.
- If you are sensitive to any type of food or medicine, inform the doctor before taking this medicine.
- Discontinue treatment 4 days before undergoing skin sensitivity tests.
- Elderly patients will be more sensitive to the effects of the medicine.
- This medicine is not intended for treatment of cough and cold in children and adolescents between the ages of 12-18 years who suffer from respiratory problems.

Before treatment with Broncholate Forte, inform the doctor if:

- You are pregnant.
- Elderly patients must consult the doctor before taking this medicine, since they may be sensitive to decongestants.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking: medicines that affect the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's, antiepileptics); antidepressants (e.g., monoamine oxidase inhibitors); antihypertensives and diuretics; other cough and cold medicines; appetite suppressants; medicines that affect the

nervous system (e.g., medicines to treat narcolepsy, to treat ADD); antipsychotics; digoxin, quinidine (for the heart); antacids; furazolidone, ciprofloxacin (antibiotic); apraclonidine (for glaucoma); oxytocin; anti-allergics; opiate antagonists; anticholinergics; surgical anesthetics, narcotic analgesics; medicines for the treatment of diarrhea; medicines for the treatment of nausea; cimetidine (to treat gastric ulcer); antiviral medicines; medicines to treat migraine; alcohol

Use of the medicine and food:

Swallow the medicine with a lot of water, a little food or drink when you have heartburn.

Use of the medicine and alcohol consumption:

Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

Pregnancy and breastfeeding:

Do not take this medicine when you are pregnant or breastfeeding.

Driving and use of machines:

Use of this medicine may impair alertness and therefore requires that caution be exercised when driving a car, operating dangerous machinery and when engaging in any activity that requires alertness. Children should be cautioned against riding a bicycle or playing near the road and the like.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

Adults and children over 12 years of age: 5-10 mL 3-4 times a day.

Be sure to measure the dose with a special measuring spoon or cup, dropper, etc.

Do not exceed the recommended dose.

If your condition does not improve within 3 days, refer to a doctor.

Do not use this medicine often or for a prolonged period without consulting a doctor.

If you took an overdose or if a child has 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. Do not induce vomiting unless explicitly instructed to do so by the doctor!

Adhere to the treatment regimen 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 the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Broncholate Forte 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.

Stop using the medicine and refer to a doctor immediately if the following occur:

- Breathing difficulties, fainting, fever, flushing, increased sweating, swelling of the face, neck, tongue or throat, severe skin rash with irritation, itching or stomach pain (may indicate a severe allergic reaction).

- Heart rhythm disturbances, palpitations, hypertension, anxiety, tremor.
- Hallucinations and paranoia (rare).
- Difficulty/pain when passing urine, urinary retention.
- Extreme somnolence, weakness, tiredness, dizziness, vertigo, seizures, fits, increased intracranial pressure (eye pain, vision changes or headache in between the eyes), blurred or double vision, constriction of pupils, headache, glaucoma (increased intraocular pressure).
- Mood changes, depression, hallucinations, nervousness, restlessness, insomnia, nightmares, confusion, excitability.
- Changes in heart rhythm, strong or irregular heart beats, a drop in blood pressure, decreased libido, breathing difficulty low body temperature, nausea or vomiting, constipation, dry mouth, coordination problems, problems in the digestive system or liver, sensitivity to light, decreased sensation, muscle pain and stiffness, numbness, muscle tremor and sensation of instability, blood circulation disturbances (such as a cold sensation in the hands and legs).

If one of the side effect worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health via the online side effects reporting form that can be found on the homepage of the Ministry of Health www.health.gov.il or through the following link: <https://forms.gov.il/globaldata/getsequeance/getsequeance.aspx?formType=AdversEffectMedic@moH.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- 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.
- Store below 25°C.
- Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to discard of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Sugar, Sorbitol 70% Sol., Alcohol 95%, Potassium Citrate, Sodium Benzoate, Citric Acid, Sodium Saccharine, Cherry Flavour, Ponceau 4R, Purified Water.

Each 5 mL contain 2.5 gram sugar, approximately 25 mg sodium, 150 mg preservative (sodium benzoate)

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

The package contains a red, clear liquid in a 120 mL bottle.

Registration holder, manufacturer and address: Sam-On Ltd., 25 Haavoda Street, Bat-Yam.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 66-84-27528

This leaflet was checked and approved by the Ministry of Health on 2/2016.