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 in August 2007

Broncho-D Syrup

Composition: Each teaspoonful (5 ml) contains:

Diphenhydramine HCI 10 mg Ammonium Chloride 136 mg

Inactive ingredients: Sodium Citrate, Citric Acid, Sodium Saccharine, Alcohol 95%, Nipagin, Menthol, Liquorice, Vino Grape, Sorbitol, Purified

Each teaspoonful contains 14.5 mg sodium.

Therapeutic activity: This preparation contains: An antihistaminic substance active against cough and congestion resulting from allergy or cold. An expectorant.

Indications: This medicine is intended for the relief of cough and respiratory tract congestion.

When should this preparation not be used?

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

Do not use in neonates or in an acute asthma attack, urinary retention

prostate enlargement, and narrow angle glaucoma.

Do not use this medicine concomitantly with a monoamine oxidase inhibitor (MAOI) or if you used an MAOI in the last two weeks.

Do not start to use this medicine without first consulting your physician: If you are pregnant. If you suffer or have suffered in the past from impaired function of the respiratory system (e.g. asthma), the heart and/or blood vessels, hypertension, the eyes (e.g. glaucoma), the liver, the kidney/urinary tract, the gastrointestinal tract (e.g. ulcer), the thyroid, from prostate enlargement. In case of prolonged or chronic cough or if the cough is accompanied by excessive phlegm, consult your doctor. The elderly should consult their physician prior to using this preparation since they are more susceptible to the side effects. The syrup does not contain sugar and is therefore suitable for diabetics, after consultation with a

How this medicine may affect your daily life?

Use of this medicine may impair alertness and therefore caution should be exercised when driving a car, operating dangerous machinery and in any activity requiring alertness. Children should be cautioned against engaging in activities such as bicycle riding or playing near traffic etc.

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

Warnings: Do not use this medicine frequently or for a prolonged period without consulting your physician. If you are sensitive to any kind of food or drugs inform your physician before taking this medicine.

Drug interactions: If you are taking another drug or if you have just finished treatment with another medicine, inform the treating physician in order to prevent hazards or inefficacy arising from drug interactions, especially for drugs from the following groups: sedatives and hypnotics, antidepressants (especially monoamine oxidase inhibitors), anticholinergic drugs (such as atropine), codeine, drugs for allergies (antihistamines).

Side effects: In addition to the desired effect of the medicine, during treatment unwanted side effects may occur, such as: dryness of the mouth, nose and throat, rash, nausea and vomiting, drowsiness, redness in the mouth, dizziness, digestive disturbances, difficult urination.

Side effects demanding special attention (usually resulting from an overdose): Consult your physician if the above-mentioned effects become pronounced or if there is a vision disturbance, confusion, sleep disorders or perspiration. If weakness, sore throat, fever, bleeding, shortness of breath, spasms, a drop in blood pressure (feeling of fainting) or rapid heart beat appear, stop treatment and consult your physician immediately. If at any time you experience side effects that are not mentioned in this leaflet, or if you notice any change in your general well-being, consult your physician immediately.

Adverse reactions and drug interactions in children and infants: Parents should report to the treating physician any side effect and also any additional medicines taken by the child!

See the above section on special side effects and drug interactions

Dosage: Unless otherwise directed by the physician, the recommended dosage is: Adults: 3 teaspoonsful (15 ml) every 4 hours.

Children 6-14 years old: 1-2 teaspoonsful (5-10 ml) every 4 hours. Use in children 1-6 years of age requires a physician's prescription. This medicine is not recommended for children under the age of 1 year.

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

Directions for use: This medicine should be taken with a meal.

<u>Prevent poisoning!</u> This medicine, like all medicines, should be kept in a closed cupboard, out of the reach of children and/or infants in order to a closed cuploard, out of the reach of children and/or liniarits 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 the original packaging. Do not induce vomiting without explicit instructions from the physician! Do not take any medicine in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

Storage: Store below 25°C. After first opening, can be used for 6 months. 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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