

BRONKIDS - chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Portal Pharmaceutical

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Bronkids Liquid

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Chlorpheniramine Maleate 4 mg

Dextromethorphan Hydrobromide 10 mg

Phenylephrine Hydrochloride 10 mg

Purpose

Antihistamine

Antitussive

Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

- if you are taking a prescription monamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease

- diabetes

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- cough or nasal congestion persists for more than 7 days, tends to recur, or is accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition
- nervousness, dizziness, or sleeplessness occur
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and over	1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 6 teaspoonfuls in 24 hours
Children 6 to under 12 years of age:	1/2 teaspoonful (2.5 mL) every 4 to 6 hours, not to exceed 3 teaspoonfuls in 24 hours
Children under 6 years of age:	Consult a doctor

Other information

Store at controlled room temperature 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container with a child-resistant cap.

Inactive ingredients

Citric Acid, FD&C Red #40, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol, and Strawberry Flavor.

Questions? Comments?

Reports of serious side effects associated with use of the product call 787-832-6645.

Rev. 08/11

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel and side panel for 118 mL label:

NDC 49963-532-04

Antihistamine/Antitussive/Nasal Decongestant

Bronkids Liquid

Strawberry Flavor

Each 5 mL (one teaspoonful) for oral administration contains:

Chlorpheniramine Maleate.....4 mg
Dextromethorphan Hydrobromide.....10 mg
Phenylephrine Hydrochloride.....10 mg

Gluten Free


**4 fl oz
(118 mL)**

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

Manufactured for:
PORTAL
Pharmaceutical
Mayaguez, PR 00680



<p>Drug Facts (continued)</p> <p>Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:</p> <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes ■ cough due to minor throat and bronchial irritation ■ nasal congestion ■ reduces swelling of nasal passages <p>Warnings Do not exceed recommended dosage.</p> <p>Do not use this product</p> <ul style="list-style-type: none"> ■ if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. 	<p>Drug Facts (continued)</p> <p>Ask your doctor before use if you have</p> <ul style="list-style-type: none"> ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ a persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ cough that occurs with too much phlegm (mucus) ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ excitability may occur, especially in children ■ may cause marked drowsiness ■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect ■ avoid alcoholic beverages 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ use caution when driving a motor vehicle or operating machinery <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ cough or nasal congestion persists for more than 7 days, tends to recur, or is accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition. ■ nervousness, dizziness, or sleeplessness occur ■ new symptoms occur <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
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BRONKIDS
chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49963-532
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	4 mg in 5 mL
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid (UNII: 2968PHW8QP)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0K00R)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49963-532-04	118 mL in 1 BOTTLE		
2	NDC:49963-532-01	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/10/2011	

Labeler - Portal Pharmaceutical (831005199)