

BIO-B KIDS- dextromethorphan, chlorpheniramine maleate, phenylephrine liquid
Advanced Generic Corporation

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.

Drug Facts

Active Ingredients : (in each 5 mL tsp.)	Purpose
Chlorpheniramine Maleate 4 mg.....	Antihistamine
Dextromethorphan Hydrobromide 15 mg.....	Cough Suppressant
Phenylephrine HCl 10 mg.....	Decongestant

Uses

- temporarily relieves these symptoms due to cold, hay fever or other upper respiratory allergies
- runny nose, sneezing, itching of the nose or throat, and itchy watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion

Warnings

- **ask your doctor before use if you have**
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

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

Warning

Do not use If you are now 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 you are taking a prescription drug that contains an MAOI; ask your doctor or pharmacist before taking this product.

Stop Use and ask a doctor if

- You get nervous, dizzy or sleepless
- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

When using this product

- do not exceed recommended dosage
- may cause excitability especially in children
- may cause drowsiness, alcohol, sedatives, tranquilizers may increase the drowsiness effect

- avoid alcoholic beverage while taking this product
- use caution when driving a motor vehicle or operating machinery

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

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

Directions Do not exceed 6 doses in 24 hours.

adults and children 12 years of age and over take 1 teaspoonful (5 mL) every 4 to 6 hours

children 6 to under 12 years of age take 1/2 teaspoonful (2.5 mL) every 4 to 6 hours

children under 6 years of age consult a doctor

Other information store at room temperature 15°- 30°C (59° - 86°F). Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering



Tamper Evident Feature: Do not use if seal under cap (or cello-band over cap) is torn, broken or missing.

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, FL 33166.

www.advancedgeneric.com

Inactive ingredients Glycerin, propylene glycol, methylparaben, propylparaben, saccharin sodium, citric acid, sodium citrate, FD and C Red No. 40, strawberry flavor and purified water

<p>Drug Facts</p> <p>Active ingredients (in each 5 mL tsp.) Purpose</p> <p>Chlorpheniramine Maleate..... 4 mg..... Antihistamine Dextromethorphan HBr..... 15 mg..... Cough Suppressant Phenylephrine HCl..... 10 mg..... Nasal Decongestant</p> <p>Uses temporarily relieves these symptoms due to cold, hay fever or other upper respiratory allergies • runny nose, sneezing, itching of the nose or throat, and itchy watery eyes • cough due to minor throat and bronchial irritation • nasal congestion</p> <p>Ask your doctor before use if you have • heart disease • diabetes • high blood pressure • thyroid disease • glaucoma • trouble urinating due to an enlarged prostate gland • cough that occurs with too much phlegm (mucus) • chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema.</p> <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>Warning do not use 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> <p>Stop Use and ask a doctor if you get nervous, dizzy or sleepless • symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.</p> <p>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.</p> <p>When using this product, do not exceed recommended dosage</p> <p>• Bronkids® Liquid is a registered trademark of Portal Pharmaceutical</p>	<p>NDC 45737-218-16</p> <p>BIO-B kids liquid</p>  <ul style="list-style-type: none"> • Antihistamine • Cough Suppressant • Nasal Decongestant <p>Contains the same active ingredients as Bronkids® Liquid⁺</p> <p>Strawberry Flavor</p> <p>Manufactured For:</p>  <p>advanced generic corporation Miami, FL 33166 www.advancedgeneric.com</p>	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • When using this product • do not exceed recommended dosage • may cause excitability especially in children • may cause drowsiness, alcohol, sedatives, tranquilizers may increase the drowsiness effect • avoid alcoholic beverage while taking this product • use caution when driving a motor vehicle or operating machinery <p>Directions Do not take more than 6 doses in 24 hours.</p> <table border="1"> <tr> <td>Adults and children 12 years of age and over</td> <td>1 tsp (5 mL) every 4 to 6 hours</td> </tr> <tr> <td>Children 6 to under 12 years of age</td> <td>1/2 tsp (2.5 mL) every 4 to 6 hours</td> </tr> <tr> <td>Children under 6 years of age</td> <td>Consult a doctor</td> </tr> </table> <p>Other information • Store at room temperature 15-30° C (59-86° F). Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering.</p> <p>Inactive ingredients glycerin, propylene glycol, methylparaben, propylparaben, saccharin sodium, citric acid, natrasol, sodium citrate, FD&C Red #40, strawberry flavor and purified water.</p> <p>Questions or comments? 1-305-403-3788</p> <p>Manufactured For: Advanced Generic Corporation, Miami, FL 33166. www.advancedgeneric.com</p>	Adults and children 12 years of age and over	1 tsp (5 mL) every 4 to 6 hours	Children 6 to under 12 years of age	1/2 tsp (2.5 mL) every 4 to 6 hours	Children under 6 years of age	Consult a doctor
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<p>Lot #: _____ Rev. 01/11</p> <p>Exp. Date: _____</p>	<p>3 45737 21816 9</p>	<p>3 45737 21816 9</p>						

BIO-B KIDS

dextromethorphan, chlorpheniramine maleate, phenylephrine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-218	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	15 mg in 5 mL	
	CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 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 Monohydrate (UNII: 2968PHW8QP)			
	Water (UNII: 059QF0KO0R)			
	Methylparaben (UNII: A2I8C7HI9T)			
	Propylparaben (UNII: Z8IX2SC1OH)			
	Propylene Glycol (UNII: 6DC9Q167V3)			
	Sodium Citrate (UNII: 1Q73Q2JULR)			
	Saccharin Sodium (UNII: SB8ZUX40TY)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	FD&C RED NO. 40 (UNII: WZB9127XOA)			
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	STRAWBERRY (Strawberry Flavor)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-218-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/01/2009		

Labeler - Advanced Generic Corporation (831762971)