BIONATUSS DXP- dexbrompheniramine maleate, dextromethorphan, 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**
Dexbrompheniramine Maleate.....2mg	Antihistamine
Dextromethorphan HBr.....20mg	Cough Suppressant
Phenylephrine HCL.....10mg	Nasal Descongestant

Purpose

Antihistamine

Cough Suppressant

Nasal Decongestant

Uses

- helps to control the relex that causes coughing
- temporarily relieves nasal congestion due to common cold, hay fever, or other upper respiratory allergies (allergic rhinitis)
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings:

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 your prescription contains an MAOI, ask a doctor or pharmacist before using the product.

Ask a doctor before use if you have

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

Ask a docotor before use if you are taking sedatives or tranquilizers

When using this product

- do not exceed recommended dose
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic beverages

- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- cough lasts for more than 7 days, comes back, or occurs with a fever, rash, or headache that lasts.
- These could be signs of a serious condition.

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

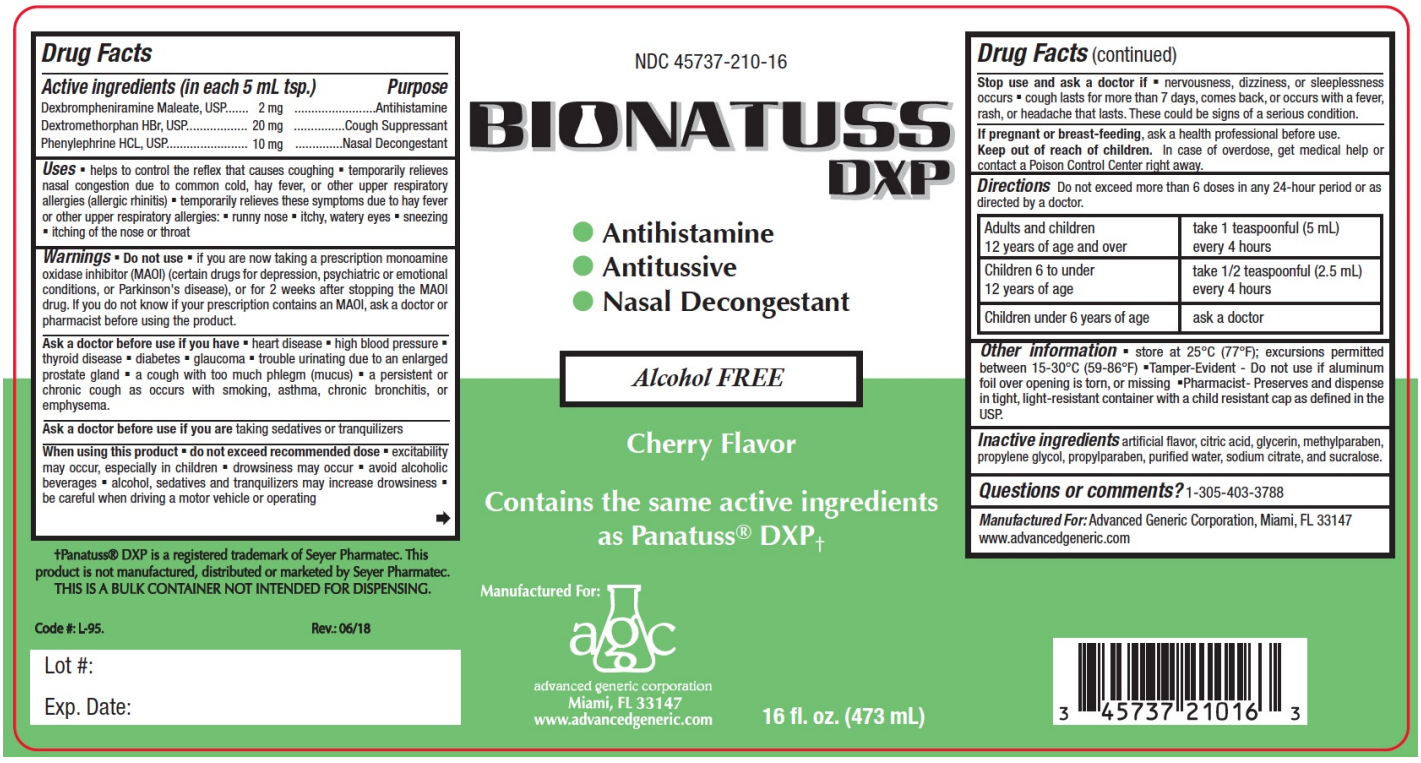
If pregnant or breast-feeding, ask a health professional before use.

Directions: Do not exceed more than 6 doses in any 24-hour period or as directed by a doctor.

Adults and children 12 years of age and over	take 1 teaspoonful (5 mL) every 4 hours
Children 6 to under 12 years of age	take 1/2 teaspoonful (2.5 mL) every 4 hours
Children under 6 years of age	ask a doctor

Inactive ingredients: artificial flavor, citric acid, glycerin, methylparaben, propylene glycol, propylparaben, water, sodium citrate and sucralose.

Questions or comments? 1-305-403-3788



BIONATUSS DXP

dexbrompheniramine maleate, dextromethorphan, phenylephrine liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45737-210
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	RASPBERRY (Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-210-16	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)

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