BIO-RYTUSS- chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride 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 2 mg Antihistamine

Dextromethorphan Hydrobromide 10 mg Cough Suppressant

Phenylephrine Hydrochloride 5 mg Nasal Decongestant

Purpose

Antihistamine

Cough Suppressant

Nasal Decongestant

Warnings

Ask doctor before use if you have

- Cough that occurs with too much phlegm (mucus), or a breathing problem or persitent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- Heart disease
- High blood pressure
- Thyroid Disease
- Diabetes
- Difficulty in urinating due to enlarged prostate gland
- Glaucoma

Ask doctor or pharmacist before use if you are taking any other oral nasal decongestant or stimulant; taking sedatives or tranquilizers.

When using this product

- Do not use more than directed
- May cause marked drowsiness; avoid alcohol beverages; alcohol, sedatives and tranquilizers may increase drowsiness.
- Be careful when driving a motor vehicle or operating machinery; excitability may occur, especially with children.

Do not use

- To sedate a child or to make a child sleepy
- 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 that contains an MAOI, ask your doctor or pharmacist before taking this product

Stop use and ask a doctor if you

• you get nervous, dizzy or sleepless

- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headaches. 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 immediately

If pregnant or breast-feeding, ask a doctor before use

Directions do not take more than 6 doses in any 24 hour period

	2 teaspoonful (10 mL) every 4-6 hours
	1 teaspoonful (5 mL) every 4-6 hours
ICHILATON / TO LINAOT IS VOSTE OF SAG	1/2 teaspoonful (2.5 mL) every 4-6 hours

Uses

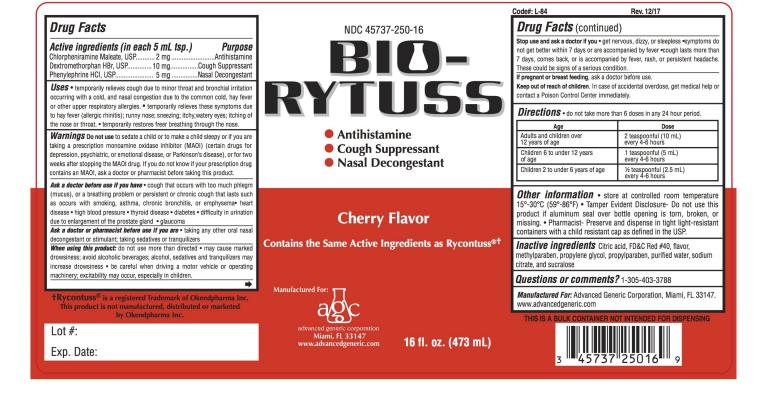
- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold, and nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis); runny nose; sneezing; itchy watery eyes; itching of the nose or throat
- temporarily restores freer beathing through the nose.

Inactive ingredients

Citric acid, FD&C Red #40, flavor, methylparaben, propylene glycol, propylparaben, purified water, Sodium citrate, sucralose.

Questions or comments?

1-305-403-3788



BIO-RYTUSS

chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-250
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY (cherry flavor)	Imprint Code	
Contains			

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:45737-250-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2012	

Labeler - Advanced Generic Corporation (831762971)

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