

**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.*

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**Drug Facts**

<b>Active ingredients (in each 5 mL tsp.)</b>	<b>Purpose</b>
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 persistent 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

adults and children 12 years of age	2 teaspoonful (10 mL) every 4-6 hours
children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4-6 hours
children 2 to under 6 years of age	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 breathing 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

Code#: L-84
Rev. 12/17

**Drug Facts**

**Active ingredients (in each 5 mL tsp.) Purpose**

Chlorpheniramine Maleate, USP..... 2 mg.....Antihistamine

Dextromethorphan HBr, USP..... 10 mg.....Cough Suppressant

Phenylephrine HCl, USP..... 5 mg.....Nasal Decongestant

**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 breathing through the nose.

**Warnings** Do not use to sedate a child or to make a child sleepy or if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional disease, or Parkinson's disease), or for two 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** • cough that occurs with too much phlegm (mucus), or a breathing problem or persistent 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 urination due to enlargement of the prostate gland • glaucoma

**Ask a 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 alcoholic beverages; alcohol, sedatives and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery; excitability may occur, especially in children.

NDC 45737-250-16

# BIO- RYTUSS

- Antihistamine
- Cough Suppressant
- Nasal Decongestant

**Cherry Flavor**

Contains the Same Active Ingredients as Rycontuss®†

**Drug Facts (continued)**

Stop use and ask a doctor if 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 headache. These could be signs of a serious condition.

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

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

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

Age	Dose
Adults and children over 12 years of age	2 teaspoonful (10 mL) every 4-6 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4-6 hours
Children 2 to under 6 years of age	½ teaspoonful (2.5 mL) every 4-6 hours

**Other information** • store at controlled room temperature 15°-30°C (59°-86°F) • Tamper Evident Disclosure- Do not use this product if aluminum seal over bottle opening is torn, broken, or missing. • Pharmacist- Preserve and dispense in tight light-resistant containers with a child resistant cap as defined in the USP.

**Inactive ingredients** Citric acid, FD&C Red #40, flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose

**Questions or comments?** 1-305-403-3788

**Manufactured For:** Advanced Generic Corporation, Miami, FL 33147. [www.advancedgeneric.com](http://www.advancedgeneric.com)

Manufactured For: advanced generic corporation  
Miami, FL 33147  
[www.advancedgeneric.com](http://www.advancedgeneric.com)

16 fl. oz. (473 mL)

Lot #:

Exp. Date:

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING

3 45737 25016 9

# BIO-RYTUSS

chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45737-250
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (cherry flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	

