

BIOGTUSS- dextromethorphan, guaifenesin, 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
Guaifenesin 300 mg	Expectorant
Dextromethorphan Hydrobromide 15 mg.....	Cough Suppressant
Phenylephrine HCl 10 mg.....	Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus
- temporarily relieves nasal congestion and cough due to minor throat and bronchial irritation occurring with the common cold or inhaled irritants.

Warnings

- Do not exceed recommended dosage
- A persistent cough may be a sign of a serious condition. If cough persists for more than a week, tends to reoccur or is accompanied by a fever, rash or persistent headache, consult a doctor
- May cause or aggravate constipation
- If nervousness, dizziness or sleeplessness occur, discontinue use and consult a doctor
- If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor.

Do not Use

- For persistent cough such as occurs with smoking, asthma, chronic bronchitis, emphysema or where cough is accompanied by excessive phelgm (mucus), unless directed by a doctor
- If you have a chronic pulmonary disease or shortness of breath, children who are taking other drugs, unless directed by a doctor. 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.

If you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to the enlargement of the prostate gland unless directed by a doctor.

Keep out of reach of children.

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 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

Other information store at room temperature 15°- 30°C (59° - 86°F).

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

Warning:Phenylketonuric. Contains 17 mg of Phenylalanine per 5 mL (one teaspoonful dose).

Inactive Ingredients aspartame, citric acid, D and C Red No 33, FD and C Blue No 1, glycerine, hydroxymethyl cellulose, methylparaben, natural and artificial flavors, propylene glycol, propylparaben, purified water, sodium citrate

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, Fl 33166

www.advancedgeneric.com

Drug Facts

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

Dextromethorphan HBr.....15 mg.....Cough Suppressant

Guaifenesin.....300 mg.....Expectorant

Phenylephrine HCl.....10 mg.....Nasal Decongestant

Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus ■ temporarily relieves nasal congestion and cough due to minor throat and bronchial irritation occurring with the common cold or inhaled irritants.

Warnings ■ Do not exceed recommended dosage ■ A persistent cough may be a sign of a serious condition. If cough persists for more than a week, tends to recur or is accompanied by a fever, rash or persistent headache, consult a doctor. ■ May cause or aggravate constipation ■ If nervousness, dizziness or sleeplessness occur, discontinue use and consult a doctor ■ If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor.

When using this product, **do not exceed recommended dosage**

Do not Use ■ For persistent cough such as occurs with smoking, asthma, chronic bronchitis, emphysema or where cough is accompanied by excessive phlegm (mucus), unless directed by a doctor ■ If you have a chronic pulmonary disease or shortness of breath, children who are taking other drugs, unless directed by a doctor.

†Giltuss® is a registered trademark of Gil Pharmaceutical Corp.

NDC 45737-205-16

BioGtuss

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Alcohol FREE • Sugar FREE

Contains the same active ingredients as

Giltuss®[†]

Grape Flavor

Manufactured For:

advanced generic corporation
Miami, Fl 33166
www.advancedgeneric.com

16 fl. oz. (473 mL)

Drug Facts (continued)

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.

If you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ difficulty in urination due to the enlargement of the prostate gland unless directed by a doctor.

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 Do not exceed 6 doses in 24 hours.

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

Other information ■ store at room temperature 15°- 30°C (59° - 86°F).

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

Warning: Phenylketonuric - Contains 17mg of Phenylalanine per 5 mL (one teaspoonful dose).

Inactive ingredients aspartame, citric acid, D&C Red #33, FD&C Blue #1, glycerin, hydroxymethyl cellulose, methylparaben, natural & artificial flavors, propylene glycol, propylparaben, purified water, sodium citrate.

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, Fl 33166, www.advancedgeneric.com

Lot #: SMP 1859 4/14/09

Exp. Date:

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BIOGTUSS

dextromethorphan, guaifenesin, phenylephrine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-205
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

Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	300 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0K00R)	
Methylparaben (UNII: A2I8C7H9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Aspartame (UNII: Z0H242BBR1)	
D&C Red No. 33 (UNII: 9DBA0SBB0L)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Hydroxymethyl Cellulose (UNII: 273FM27VK1)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (Grape Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-205-16	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)