

BIO-G-TUSS PEDIATRIC DROPS- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

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.

Active ingredients

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCl

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves nasal congestion due to hay fever or other respiratory allergies (allergic rhinitis) and cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

Do not exceed recommended dosage

- If nervousness, dizziness, or sleeplessness occurs, 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 this product

- for persistent or chronic cough such as occurs with asthma, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor
- in a child who is taking a prescription Monoamine oxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for two weeks after stopping the MAOI drug; if you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor.

Stop use and ask a doctor

- A persistent cough may be a sign of a serious condition
- if cough persists for more than one week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

Keep out of reach of children

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

Control Center right away.

Directions

Age	Dose
children 6 to under 12 years of age	2 mL every 6-8 hours
children 2 to under 6 years of age	1 mL every 6-8 hours
children under 2 years of age	consult a doctor

Inactive ingredients

citric acid, grape flavor, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate, sucralose.

Questions or Comments

1-305-403-3788

Drug Facts

Active Ingredients (in each 1mL)	Purpose
Dextromethorphan HBr.....7.5mg.....	Cough Suppressant
Guafenesin.....88mg.....	Expectorant
Phenylephrine HCl.....2.5mg.....	Nasal Decongestant

Uses: • helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive • temporarily relieves nasal congestion due to hay fever or other upper respiratory allergies (allergic rhinitis) and cough due to minor throat and bronchial irritation as may occur with the common cold.

Warnings: Do not exceed recommended dosage. • If nervousness, dizziness, or sleeplessness occurs, 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 this product: for persistent or chronic cough such as occurs with asthma, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor. • in a child who is taking a prescription Monoamine oxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for two weeks after stopping the MAOI drug; If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

• Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor.

• Stop use and ask a doctor. • A persistent cough may be a sign of a serious condition; • if cough persists for more than one week, tend to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

†Giltuss® Pediatric Drops is a registered trademark of Gil Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Gil Pharmaceutical Corp.

NDC: 45737-240-02

BIO-G-TUSS

PEDIATRIC DROPS

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Sugar Free Dye Free Alcohol Free

Contains the same active ingredients as Giltuss® Pediatric Drops†

Manufactured For:

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

Grape Flavor

2 fl. oz. (60 mL)

Drug Facts (cont.)

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

Directions: Do not exceed recommended dose. Measure with the dosage device provided.

Age	Dose
children 6 to under 12 years of age	2 mL every 6-8 hours
children 2 to under 6 years of age	1 mL every 6-8 hours
children under 2 years of age	consult a doctor

Other information: • Store at room temperature 15°-30°C (59-86°F)
Tamper evident: Do not use if there is evidence of tampering.

Inactive ingredients: citric acid, grape flavor, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate, sucralose.

Questions or comments? 1-305-403-3788

Manufactured for: Advanced Generic Corporation, Miami, FL 33166
www.advancedgeneric.com

Lot #/Exp: _____ Rev: 04/14

NON-VARNISH

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BIO-G-TUSS PEDIATRIC DROPS

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-240
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 1 mL

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	00 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-240-02	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2016	

Labeler - Advanced Generic Corporation (831762971)

Revised: 9/2016

Advanced Generic Corporation