BIO-G-TUSS PEDIATRIC DROPS- dextromethorphan hbr, guaifenes in, 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 lossen phlegm (mucus) and thin bronchial secretions to drain broncial 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 ocurs, discontinue use and consult a doctor
- If symptoms do not improve wihtin 7 days or are accompanied by fever, consult a doctor.

Do not use this product

- for persistant 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 Monoaminooxidase 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 onweek, tend 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

Directions

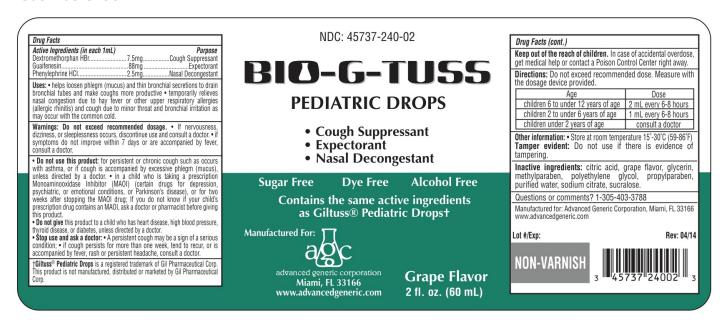
Age	Dose	
children 6 to under 12 years of age	2 mL every 6-8 hours	
chidren 2 to under 6 years of age	1 mL every 6-8 hours	
children under 2 years of age	consult a doctor	

Inactive ingredients

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

Questions or Comments

1-305-403-3788



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: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 1 mL	

I	GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENES IN	in 1 mL
	PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

l	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	0 4/0 1/20 16	

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)

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