BIOGTUSS TR- guaifenesin, phenylephrine hcl, dextromethorphan hbr tablet
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 (in each tablet) Purpose

Dextromethorphan HBR .... 28 mg ..... Cough Suppressant

Guaifenesin ..... 388 mg ..... Expectorant

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

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses

Temporarily relieves these symptoms associated with a cough, the common cold, hay fever, or other upper respiratory allergies

- helps loosen phlegm (mucus)
- loosens nasal congestion
- thin bronchial secretions
- drain bronchial tubes
- cough and coughing and calms the cough control center
- make coughs more productive
- clears stuffy nose
- clear nasal passageways
- shrinks swollen membranes

Warnings

Do not exceed recommended dosage

Do not use this product if you are taking a 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 are uncertain whether your prescription drug contains an MAOI, ask a health professional.

Ask a doctor before use if you have:

- heart disease
- excessive phlegm (mucus)
- high blood pressure
- diabetes
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product do not use more than directed

Stop use and ask a doctor if:

- Nervousness, dizziness, or sleeplessness occurs

- symptoms are accompanied by fever, rash, persistent headache, or excessive phlegm (mucus)
- cough and congestion do not improve within 7 days or are accompanied by fever or symptoms tend to recur.

If pregnant or breast-feeding. Ask a health professional before use.

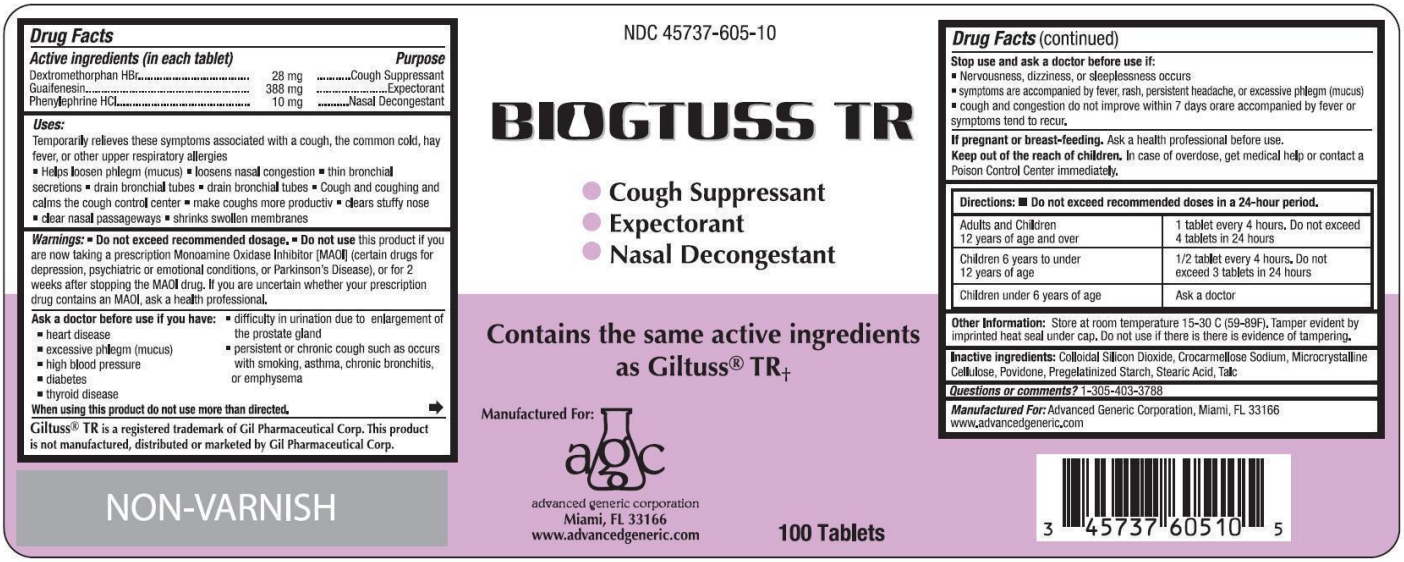
Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions: Do not exceed recommended doses in a 24-hour period

Adults and children 12 years of age and over	1 tablet every 4 hours. Do not exceed 4 tablets in 24 hours
Children 6 to 12 years of age	1/2 tablet every 4 hours. Do not exceed 3 tablets in 24 hours
Children under 6 years of age	Ask a doctor

Inactive ingredients: Colloidal silicon dioxide, crocarmellose sodium, microcrystalline cellulose, povidone, pregelatinized starch, stearic acid, talc

Questions or comments? 305-403-3788



BIOGTUSS TR

guaifenesin, phenylephrine hcl, dextromethorphan hbr tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45737-605
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	388 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	28 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	BG;AGC
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45737-605-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2014	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph final	part341	04/01/2014	

Labeler - Advanced Generic Corporation (831762971)

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