

BIOPHEX TR- guaifenesin, phenylephrine hcl 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
Guaifenesin 388 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal Decongestant

□ Purpose

□ 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 congestions
- thin bronchial secretions
- drain bronchial tubes
- 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

□ 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 6 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, hydroxy propyl methyl cellulose (HPMC), microcrystalline cellulose, polyethylene glycol 400 (PEG-400), povidone, pregelatinized starch, stearic acid, talc

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

Drug Facts

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Guaifenesin.....	388 mgExpectorant
Phenylephrine HCl.....	10 mgNasal Decongestant

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Gilphex® is a registered trademark of Gil Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Gil Pharmaceutical Corp.

NDC 45737-606-10

BIOPHEX TR

● Expectorant
● Nasal Decongestant

Contains the same active ingredients as Gilphex® TR₊

Manufactured For:



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

100 Tablets

Drug Facts (continued)

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Children under 6 years of age	Ask a doctor

Other Information: Store at room temperature 15-30 C (59-86F). Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering.

Inactive Ingredients: Colloidal Silicon Dioxide, Crocarmellose Sodium, Hydroxy Propyl Methyl Cellulose (HPMC), Microcrystalline Cellulose, Polyethylene Glycol 400 (PEG-400), Povidone, Pregelatinized Starch, Stearic Acid, Talc

Questions or comments? 1-305-403-3788

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

NON-VARNISH



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BIOPHEX TR

guaifenesin, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-606
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

Inactive Ingredients

Ingredient Name	Strength
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	BP;AGC
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-606-10	100 in 1 BOTTLE		

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)