BIOPHEX TR- guaifenes in, 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

Phenylephrine HCl 10 mg Nasal Decongestant

Purpose

[Expectorant

Nasal Decongestant

Uses

^ITemporarily 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:

- Dheart 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:

- INervousness, 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. IAsk a health professional before use.

IKeep 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

DAdults and children 12 years of age and over 24 hours

1 tablet every 4 hours. Do not exceed 6 tablets in

Children 6 to 12 years of age 24 hours

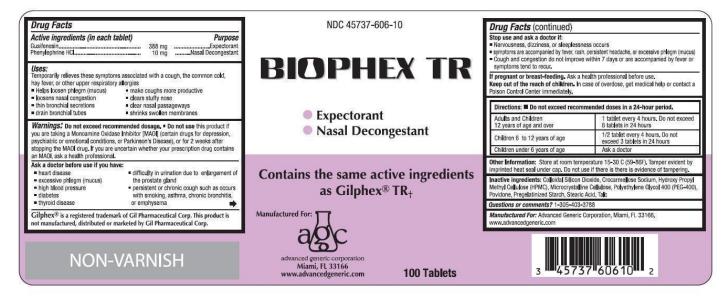
1/2 tablet every 4 hours. Do not exceed 3 tablets in

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



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 HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 10 mg UNII:1WS297W6MV) HYDROCHLORIDE **Inactive Ingredients Ingredient** Name Strength COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

			1)				
HYDROXYPROPYL CE	LLULOSE (UNII: RFW	2ET671P)					
CELLULOSE, MICROC	RYSTALLINE (UNII: (OP1R32D61U)					
POLYETHYLENE GLY	C OL 400 (UNII: B6978	394SGQ)					
PO VIDO NE (UNII: FZ98	9GH94E)						
STARCH, PREGELATIN	J IZED CORN (UNII: O	3232NY3SJ)					
STEARIC ACID (UNII: 4)	ELV7Z65AP)						
TALC (UNII: 7SEV7J4R1	U)						
Product Character	ristics						
Color	white	Score	Score			no score	
Shape	OVAL	Size	Size		18 mm		
Flavor		Imprint	Imprint Code		BP;AGC		
Contains							
Packaging							
	Package D	Package Description		Marketing Start Date		Marketing End Date	
# Item Code		100 in 1 BOTTLE					
	100 in 1 BOTTLE	1					
# Item Code 1 NDC:45737-606-10	100 in 1 BOTTLE	1					
	100 in 1 BOTTLE						
1 NDC:45737-606-10							
1 NDC:45737-606-10							
			ph Citation	Marketing Start	Date	Marketing End Date	

Labeler - Advanced Generic Corporation (831762971)

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