

GUAIFENESIN- guaifenesin tablet
Pharbest Pharmaceuticals, Inc.

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.

Drug Facts

Active Ingredient (in each tablet)

Guaifenesin 400mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- helps make cough more productive

Warnings

Ask doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache.

These could be signs of serious illness.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- take with a full glass of water
- this product can be administered without regard for the timing of the meals
- do not exceed 6 doses in 24 hours or as directed by doctor

adults and children 12 years of age and over	take 1 tablet every 4 hours as needed
children 6 to under 12 years of age	take ½ tablet every 4 hours as needed
children under 6 years of age	consult a doctor

Other information

- store at room temperature (15°-30°C)

Inactive ingredients

magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, stearic acid.

Questions?

Adverse drug event call (866) 562-2756 Mon-Fri: 8 AM to 4 PM

PHARBEST

NDC 16103-379-04

Manufactured in the USA

Immediate Release

***COMPARE TO the active ingredient in MUCINEX® Tablets**

PHARBINEX

Guaifenesin 400mg each

Expectorant

30 TABLETS



GUAIFENESIN			
guaifenesin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-379
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg		
Inactive Ingredients				
Ingredient Name		Strength		
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	white	Score	2 pieces	
Shape	CAPSULE (CAPSULE SHAPED TABLET)	Size	17mm	
Flavor		Imprint Code	PH063	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-379-04	1 in 1 CARTON	05/01/2018	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	05/01/2018		

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(16103-379) , analysis(16103-379) , pack(16103-379) , label(16103-379)