

CHEST CONGESTION RELIEF - guaifenesin tablet

Strategic Sourcing Services LLC

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 (per tablet)

Guaifenesin 400mg

Purpose

Expectorant

Uses

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

Warnings

Ask doctor before use if you have

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

Stop use and ask doctor if

- Symptoms are accompanied by fever, rash or persistent headache
- cough persists for more than 1 week or tends to recur

A persistent cough may be a sign of a serious condition.

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 immediately.

Directions

- **Adults and children 12 years of age and over:** take 1 tablet every 4 hours as needed
- **Children 6 to 10 under 12 years of age:** take 1/2 tablet every 4 hours as needed
- **Children under 6 years of age:** consult a doctor

Do not exceed 6 doses in a 24 hour period or as directed by a doctor

Other Information

store at 15°-30°C (59°-86°F)

Inactive ingredients

magnesium stearate, microcrystalline cellulose. May also contain (colloidal) silicon dioxide, (co) povidone, dicalcium phosphate, maltodextrin, sodium starch glycolate, stearic acid.



CHEST CONGESTION RELIEF

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-729
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		
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
COPOVIDONE (UNII: D9C330MD8B)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
Product Characteristics				
Color	white	Score	2 pieces	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	PH063	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-729-09	2 in 1 CARTON	08/29/2019	
1		12 in 1 BLISTER PACK; 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	08/01/2012		

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(49348-729)