REFENESEN CHEST CONGESTION RELIEF - guaifenes in tablet Rees e Pharmaceutical Co

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 Expectoran

Guaifenesin; Expectorant

helps loosen phlegm (mucus) and thin

bronchial secretions to rid the bronchial passageways of bothersome mucus

• helps make coughs more productive

Ask a Doctor before use if you have

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 (mucous)

Keep out of reach of children

In case of overdose, get medical help or contact a poison control

cenetr immediately.

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 breastfeeding, ask a health professional before use

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

DYE FREE IMMEDIATE RELEASE CAPLETS

Refenesen Chest Congestion Relief

EXPECTORAN

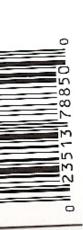
- Relieves Chest Congestion
 - Thins & Loosens Mucus



Guaifenesin 400mg

50 Caplets / Comprimidos

REESE PHARMACEUTICAL COMPANY Cleveland, Ohio 44106 1-800-321-7178 • reese@apk.net www.reesepharmaceutical.com Distributed By



Caution: do not use if imprinted seal under cap is broken or missing

Drug Facts

Purpose Expectorant Active ingredient (per caplet) Guaifenesin 400mg

USBS = helps loosen phiegm (mucus) and thin bronchia secretions to rid the bronchial passageways of bother some mucus | helps make coughs more productive

Warnings
Ask a doctor before use II you have
persistent or chronic cough, such as occurs with
persistent or chronic bronchitts or emphysema
smoking, asthma, chronic bronchitts or emphysema
cough is accompanied by excessive phiegm (mucus)

Stop use and ask a 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

If pregnant or breast-leeding, 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. condition

Directions

Adults and children 12 years of age and over: take caplet every 4 hours as needed

■ Children 6 to under 12 years of age: take 1/2 caplet every 4 hours as needed

Do not exceed 6 doses in a 24 hour period or as directed Echildren under 6 years of age; consult a doctor by a doctor

Other information store at 15'-30' C (59'-86'F)

G450 Rev. 1/09 Inactive ingredients

colloidal silicon dioxide, magnesium stearate, micro-crystalline cellulose, maltodextrin, povidone, stearic acid

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REFENESEN CHEST CONGESTION RELIEF

guaifenesin tablet

Product Information	P	rod	luct	Info	rma	tion	l
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:10956-788

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

6 · · · · · · · · · · · · · · · · · · ·				
Ingredient Name	Strength			
SILICON DIO XIDE, COLLO IDAL (UNII: ETJ7Z6 XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
STEARIC ACID (UNII: 4ELV7Z65AP)				

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	PH063
Contains			

Packaging

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:10956-788-01	1 in 1 CARTON					
1	NDC:10956-788-50	50 in 1 BOTTLE, PLASTIC					
2	NDC:10956-788-01	1 in 1 CARTON					

2 NDC:10956-788-09	100 in 1 BOTTLE, PLASTIC				
Marketing Information					
Marketing Category	Application Number or Monograph Cit	ation Marketing Start Date	Marketing End Date		
ggy			g		
OTC monograph final	part341	09/23/2003			

Labeler - Reese Pharmaceutical Co (004172052)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment				
Name	Address	ID/FEI	Business Operations	
Reese Pharmaceutical Co		004172052	relabel, repack	

Establishment					
Name	Address	ID/FEI	Business Operations		
Pharbest		557054835	manufacture		

Revised: 11/2010 Reese Pharmaceutical Co