# CVS HEALTH CHEST CONGESTION RELIEF - guaifenes in tablet CVS PHARMACY 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.

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#### **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.



CVS HEALTH CHEST CONGESTION RELIEF guaifenesin tablet				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-995	
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		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
COPOVIDONE (UNII: D9 C330 MD8 B)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

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

]	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69842-995-	1 in 1 CARTON	12/01/2013		
1		60 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	08/01/2012	

### Labeler - CVS PHARMACY INC (062312574)

## Registrant - Reese Pharmaceutical Co (004172052)

Establishment			
Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(69842-995), repack(69842-995)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(69842-995)

Revised: 7/2013 CVS PHARMACY INC