

**REFENESEN CHEST CONGESTION RELIEF - guaifenesin tablet**  
**Reese 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.*

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**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

center 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

**EXPECTORANT**

- Relieves Chest Congestion
- Thins & Loosens Mucus

**NON  
DROWSY**

**Guaifenesin 400mg**

**50 Caplets / Comprimidos**

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



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

## Drug Facts

**Active ingredient (per caplet)** Purpose  
Guaifenesin 400mg 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 a doctor before use if you have

- persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough is accompanied by excessive phlegm (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 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 caplet every 4 hours as needed
- Children 6 to under 12 years of age: take 1/2 caplet 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

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

G450 Rev. 1/09

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## REFENESEN CHEST CONGESTION RELIEF

guaifenesin tablet

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10956-788 |
| <b>Route of Administration</b> | 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 |
|--|----------|
| SILICON DIOXIDE, COLLOIDAL (UNII: ETJ7Z6XBU4)  |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)          |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) |          |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)                |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                |          |

### Product Characteristics

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | white | <b>Score</b>        | 2 pieces |
| <b>Shape</b>    | OVAL  | <b>Size</b>         | 17mm     |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | PH063    |
| <b>Contains</b> |       |                     |          |

### 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 Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| 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