

**REESE ONETAB CONGESTION AND COUGH - guaifenesin/phenylephrine 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**

Guaifenesin	400 mg
Phenylephrine HCl	10 mg
Guaifenesin	Expectorant
Phenylephrine HCl	Nasal decongestant

temporarily relieves symptoms associated with a cough ,the common cold,hay fever or other upper respiratory allergies.

helps loosen phlegm;mucus

clear nasal passageways

loosens nasal congestion

drain bronchial tubes

shrinks swollen membranes

clears stuffy nose

makes coughs more productive

do not exceed recommended dosage

Do not use this product if you are now taking a prescription Monoamine Oxidase inhibitor ; MAIO,

certain drugs for depression,psychiatric or emotional conditions, or Parkinsons Disease or for 2 weeks

after stopping the MAIO drug,if you are uncertain whether your prescription contains an MAIO ,

ask a health professional.

ask a doctor before use if you have

heart disease

high blood pressure

thyroid disease

diabetes

excessive phlegm;mucus

difficulty in urination due to an enlarged prostate gland

persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema  
stop use and ask a doctor if

nervousness, dizziness or sleeplessness occurs

symptoms are accompanied by fever, rash, persistent headache or excessive phlegm; mucus.

cough and congestion do not improve within 7 days or tend to recur

these could be signs of a serious condition

ask a health professional before use.

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 consult a doctor

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

croscarmellose sodium, hypromellose, lactose, magnesium silicate,

magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, povidone,

silica, sodium lauryl sulfate, stearic acid, titanium oxide and triacetin.

**Drug Facts (continued)**

**Other information**

- store at 15°-30°C (59°-86°F)
- caution: do not use if imprinted seal under cap is broken or missing

**Inactive ingredients** croscarmellose sodium, hypromellose, lactose, magnesium silicate, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, povidone, silica, sodium lauryl sulfate, stearic acid, titanium dioxide and triacetin

Rev 6/09 RPEROT

Distributed By  
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Questions? 800-321-7178

NDC 10958-814-30

**REESE'S ONETAB™**

**30 DOSES PER PACKAGE**

**REESE'S ONETAB™**

**INTENSE STRENGTH CONGESTION & COUGH**

Relieves nasal, sinus and chest congestion and makes coughs more productive

Guaifenesin  
Phenylephrine HCl

- EXPECTORANT
- NASAL DECONGESTANT
- NON DROWSY RELIEF

**30 DYE FREE CAPLETS**

**STRONGER THAN LEADING BRANDS**

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**30 DYE FREE CAPLETS**

**STRONGER THAN LEADING BRANDS**

Retain carton for complete product information

**Drug Facts****Active ingredients (per caplet)**

Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

**Purpose**

**Uses** temporarily relieves symptoms associated with a cough, the common cold, hay fever, or other upper respiratory allergies

■ helps loosen phlegm (mucus)	■ shrinks swollen membranes
■ thin bronchial secretions	■ clear nasal passageways
■ loosens nasal congestion	■ drain bronchial tubes
■ make coughs more productive	■ clears stuffy nose

**Warnings** Do not exceed recommended dosage  
 Do not use ■ this product if you are now taking a prescription Monoamine Oxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's Disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, ask a health professional.

**Ask a doctor before use if you have**

■ heart disease	■ high blood pressure
■ thyroid disease	■ diabetes

■ excessive phlegm (mucus)  
 ■ difficulty in urination due to enlargement of the prostate gland  
 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema

**Stop use and ask a doctor if**

- nervousness, dizziness or sleeplessness occurs
- symptoms are accompanied by fever, rash, persistent headache or excessive phlegm (mucus)
- cough and congestion do not improve within 7 days or tend to recur.

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.  
 Keep out of the 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

**REESE ONETAB CONGESTION AND COUGH**

guaifenesin/phenylephrine tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10956-814
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>LACTOSE</b> (UNII: J2B2A4N98G)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

### Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	RCCGPE;C27
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-814-01	1 in 1 CARTON		
1	NDC:10956-814-30	30 in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/01/2010	

**Labeler** - Reese Pharmaceutical Co (004172052)

### Establishment

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

Revised: 1/2011

Reese Pharmaceutical Co