## REESE ONETAB CONGESTION AND COUGH - guaifenes in/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.

-----

## **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 approve 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

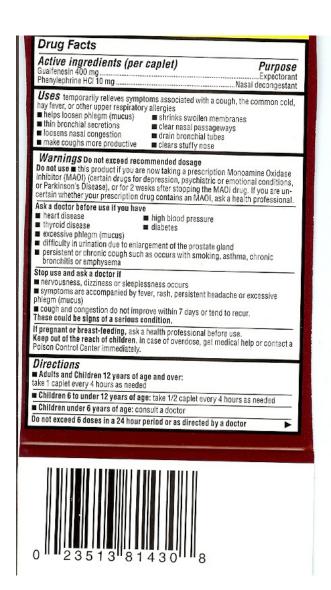
Adults and Children 12 years of age and over take 1 caplet every 4 hours as needed children 6 to under 12 years of age consult a doctor

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, mycocrystalline cellulose, mineral oil, povidone,

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





## REESE ONETAB CONGESTION AND COUGH

guaifenesin/phenylephrine tablet

P	roc	luct	Information
---	-----	------	-------------

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10956-814

Route of Administration ORAL

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

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
LACTOSE (UNII: J2B2A4N98G)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

`	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PO VIDO NE (UNII: FZ989 GH94E)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

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

Pack	aging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 ND	C:10956-814-01	1 in 1 CARTON		
1 ND	C: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