PREMIER VALUE CHEST AND SINUS CONGESTION RELIEFguaifenes in/phenylephrine tablet Chain Drug Consortium, LLC

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.

Retain carton for complete product information

Drug Facts

Active Ingredients (in each caplet)

Purpose

Guaifenesin 400 mg...... Phenylephrine HCl 10 mg.

.Expectorant .Nasal Decongestant

Uses associated with a cougn, the common other upper respiratory allergies

helps loosen phlegm (mucus)

thin bronchial secretions

clear nasal passageways

drain bronchial tubes USES associated with a cough, the common cold, hay fever, or

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 thyroid disease
- high blood pressure
 diabetes
 difficulty in urination due to enlargement of the prostate gland
- excessive phlegm (mucus)
 persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- Stop use and ask a doctor if
- Stop use and ask a doctor if
 mervousness, 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.

Drug Facts (continued)

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

Other information ■ store at 15°- 30°C (59°- 86°F ■ Caulion: 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



If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

CHAIN DRUG CONSORTIUM, LLC. BOCA RATON, FL 33431



CHEST AND SINUS

CONGESTION RELIEF NASAL DECONGESTANI

Phenylephrine HCl 10mg EXPECTORANT

Guaifenesin 400mg

- Immediate Release Caplets
- Relieves Chest & Sinus Congestion
- Thins and Loosens Mucus
- Dye-Free

50 Caplets

Provides up to 2400mg Guaifenesin and 60mg Phenylephrine HCl daily



Drug Facts

Active ingredients (per caplet)

Purpose

Guaifenesin 400 mg.Phenylephrine HCl 10 mg.

.ExpectoranNasal decongestan

- Uses temporarily relieves symptoms associated with a cough, the common cold, hay fever or other upper respiratory allergies helps loosen phlegm (mucus) thin bronchial secretions drain bronchial tubes make coughs more productive nasal congestion stuffy nose clear nasal passageways shrinks swollen membranes

Warnings See carton for complete warnings

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.



Provides up to 2400mg Guaifenesin and 60mg Phenylephrine HCl daily

Drug Facts (continued)

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: consult a docto

Do not exceed 6 doses in a 24 hour period or as directed by

Other information

■ store between 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. 11/09 RPEPV

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PREMIER VALUE CHEST AND SINUS CONGESTION RELIEF

guaifenesin/phenylephrine tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68016-021

Route of Administration

ORAL

Active Ingredient/Active Moiety

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

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)	
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			

]	Packaging					
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:68016-021- 01	1 in 1 CARTON				
1		50 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	02/01/2006	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment			
Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(68016-021), repack(68016-021)

Revised: 10/2015 Chain Drug Consortium, LLC