

REFENESEN CHEST CONGESTION RELIEF PE- 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.

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.

<p>Guarde la caja para ver toda la información del producto</p> <p>Hechos acerca del Medicamento</p> <p>Ingredientes activos (en cada comprimido) Guaifenesina 400 mg.....Expectorante HCl de Fenilefrina 10 mg.....Descongestivo nasal</p> <p>Propósito</p> <p>Usos asociado con los, catarro común, fiebre de heno u otras alergias de las vías respiratorias superiores ■ ayuda a expectorar las flemas (mucosidad) ■ despeja las vías nasales ■ alivia la nariz tapada ■ dreña las conductos bronquiales ■ reduce la congestión nasal ■ hace que la tos sea más productiva ■ alivia las secreciones bronquiales ■ reduce las membranas inflamadas</p> <p>Advertencias No exceda la dosis recomendada</p> <p>No tome ■ este producto si actualmente está tomando medicamentos de prescripción que contienen el inhibidor de Oxidasa Monoamina (MAOI) (ciertos medicamentos para la depresión, estados psiquiátricos o emocionales o Mal de Parkinson), o durante las 2 semanas siguientes a haber dejado de tomar un medicamento con MAOI. Si no está seguro(a) que su medicamento contiene el MAOI, consulte a un profesional de la salud.</p> <p>Consulte a su médico antes de tomar este medicamento en caso de tener</p> <ul style="list-style-type: none"> ■ padecimiento cardíaco ■ padecimiento de la tiroides ■ fiebre (mucosidad) excesiva ■ dolor de cabeza persistente o fiebra (mucosidad) excesiva ■ la tos y la congestión nasal no mejoran en 7 días o tienden a presentarse de nuevo. <p>Estas pueden ser señales de una condición seria.</p> <p>Si está embarazada o lactando, pregúntele a un profesional de la salud antes de usarlo.</p>	<p>Drug Facts (continued)</p> <p>Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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 <p>Do not exceed 6 doses in a 24 hour period or as directed by a doctor</p> <p>Other information ■ store at 15°-30°C (59°-86°F) ■ caution: do not use if imprinted seal under cap is broken or missing</p> <p>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 3/09 RPE</p> <p>Hechos acerca del Medicamento (continued)</p> <p>Manténgalo fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o póngase en contacto de inmediato con el Centro de Control de Envenenamientos.</p> <p>Direcciones</p> <ul style="list-style-type: none"> ■ Adultos y niños mayores de 12 años de edad: tome 1 comprimido cada 4 horas como sea necesario ■ Niños de 6 a 12 años de edad: tome 1/2 comprimido cada 4 horas como sea necesario ■ Niños menores de 6 años: consulte a su médico <p>No exceda más de 6 dosis durante un periodo de 24 horas o como se lo indique un doctor</p> <p>Otra información ■ guárdelo a 15°-30°C (59°-86°F) ■ precaución: no lo use si el sello impreso bajo la tapa está roto o ausente</p> <p>Ingredientes inactivos sodio croscarmeloso, hipromelosa, lactosa, silicato de magnesio, estearato de magnesio, maltodextrina, celulosa microcristalina, aceite mineral, povidona, sílice, lauril sulfato de sodio, ácido esteárico, dióxido de titanio y triacetina</p>	<p>Retain carton for complete product information</p> <p>Drug Facts</p> <p>Active ingredients (in each caplet) Guaifenesin 400 mg.....Expectorant Phenylephrine HCl 10 mg.....Nasal decongestant</p> <p>Purpose</p> <p>Uses temporarily relieves symptoms associated with a cough, the common cold, hay fever or other upper respiratory allergies</p> <ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) ■ clear nasal passageways ■ loosens nasal congestion ■ thin bronchial secretions ■ drain bronchial tubes ■ shrinks swollen membranes ■ clears stuffy nose ■ make coughs more productive <p>Warnings Do not exceed recommended dosage</p> <p>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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ thyroid disease ■ excessive phlegm (mucus) ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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. <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>DYE FREE IMMEDIATE RELEASE CAPLETS</p> <p>Refenesen™</p> <p>Chest Congestion Relief PE</p> <p>EXPECTORANT NASAL DECONGESTANT</p> <ul style="list-style-type: none"> • Thins & Loosens Mucus • Relieves Chest and Sinus Congestion <p>NON DROWSY</p> <p>Guaifenesin 400mg Phenylephrine HCl 10mg</p> <p>50 Caplets / Comprimidos</p>
<p>Distributed By REESE PHARMACEUTICAL COMPANY Cleveland, Ohio 44106 1-800-321-7178 • reese@apk.net www.reese-pharmaceutical.com</p> <p>0 23513 79150 0</p>			<p>5</p>

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10956-791
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (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	RCC;GPE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-791-01	1 in 1 CARTON		
1	NDC:10956-791-50	50 in 1 BOTTLE, PLASTIC		
2	NDC:10956-791-01	1 in 1 CARTON		
2	NDC:10956-791-09	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/20/2006	

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
Contract Pharmaca Corp.		057795122	manufacture

Revised: 12/2010

Reese Pharmaceutical Co