

**LEADER CHEST CONGESTION RELIEF PE- guaifenesin/phenylephrine tablet**  
**Cardinal Health**

*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.

Retain carton for complete product information

NDC 37205-874-71

**LEADER**<sup>®</sup>

**Chest  
Congestion  
Relief PE**

Guaifenesin 400mg | Phenylephrine 10mg

**Expectorant  
Nasal Decongestant**

Loosens & Relieves Chest Congestion  
Clears Nasal Stuffiness  
Immediate Release Tablets

**Drug Facts**

Active ingredients (in each tablet)	Purpose
Guaifenesin 400 mg.....	Expectorant
Phenylephrine HCl 10 mg.....	Nasal decongestant

**Uses** 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
- thin bronchial secretions
- drain bronchial tubes
- shrinks swollen membranes
- clears stuffy nose
- make coughs more productive

**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

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.



Dye-free



50 TABLETS

Guarde la caja para ver toda la información del producto

## Hechos acerca del Medicamento

### Ingredientes activos Propósito

(en cada tableta)  
 Guaifenesina 400 mg. ....Expectorante  
 HCl de Fenilefrina 10 mg. ....Descongestivo nasal

### Usos asociado con tos, 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
- drena los conductos bronquiales
- reduce la congestión nasal
- hace que la tos sea más productiva
- diluye las secreciones bronquiales
- reduce las membranas inflamadas

### Advertencias No exceda la dosis recomendada

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.

### Consulte a su médico antes de tomar este medicamento en caso de tener

- padecimiento cardíaco
- presión alta
- padecimiento de la tiroides
- diabetes
- flema (mucosidad) excesiva
- dificultad para orinar debido a un ensanchamiento de la próstata
- tos persistente o crónica como ocurre al fumar, o en asma, bronquitis crónica o enfisema

### Deje de usarlo y consulte a un médico si

- se presenta nerviosismo, mareos o insomnio
- los síntomas están acompañada con fiebre, sarpullido, dolor de cabeza persistente o flema (mucosidad) excesiva
- la tos y la congestión nasal no mejoran en 7 días o tienden a presentarse de nuevo.

Estas pueden ser señales de una condición seria.

Si está embarazada o lactando, pregúntele a un profesional de la salud antes de usarlo.

## Drug Facts (continued)

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 tablet every 4 hours as needed

■ Children 6 to 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

**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

## Hechos acerca del Medicamento (continued)

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.

### Direcciones

■ Adultos y niños mayores de 12 años de edad: tome 1 tableta cada 4 horas como sea necesario

■ Niños de 6 a 12 años de edad: tome 1/2 tableta cada 4 horas como sea necesario

■ Niños menores de 6 años: consulte a su médico

No exceda más de 6 dosis durante un periodo de 24 horas o como se lo indique un doctor

**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

**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

Rev 3/09 RPELDR



Distributed By: Cardinal Health  
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 CIN 3722899

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# LEADER CHEST CONGESTION RELIEF PE

guaifenesin/phenylephrine tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-874
<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>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>LACTOSE</b> (UNII: J2B2A4N98G)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>MAGNESIUM SILICATE</b> (UNII: 9B9691B2N9)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

## 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>	RCCGPE;C27
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-874-01	1 in 1 CARTON		
1	NDC:37205-874-71	50 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/05/2006	

**Labeler** - Cardinal Health (097537435)

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

**Establishment**

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

Revised: 1/2011

Cardinal Health