

PHARBINEX-PE- guaifenesin 400mg and phenylephrine hcl 10mg tablet, coated
Pharbest Pharmaceuticals, Inc.

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

Active ingredients (in each caplet)

Guaifenesin 400mg

Phenylephrine HCl 10mg

Purpose

Expectorant

Nasal Decongestant

Uses

Temporarily relieves symptoms associated with cough, the common cold, hay fever or upper respiratory allergies

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

Warnings

Do not exceed recommended dosage.

Do not use

- 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 MAOI drug. If you do not know whether your prescription drug contains an MAOI, ask your doctor or pharmacist before using this product.

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

These could be signs of a serious illness.

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 right away (1-800-222-1222).

Directions

- take with a full glass of water
- this product can be administered without regard for the timing of meals
- do not exceed 6 doses in 24 hours or as directed by doctor

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 ½ caplet every 4 hours as needed
children under 6 years of age	consult a doctor

Other information

- store at room temperature (15°-30°C)

Inactive ingredients

croscarmellose sodium, hypromellose, lactose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, povidone, silicon dioxide, sodium lauryl sulfate, stearic acid, titanium dioxide, triacetin

Questions?

Adverse drug event call (866) 562-2756 Mon-Fri: 8 AM to 4 PM

PHARBEST

NDC 16103-0389-04

Manufactured in the USA

Immediate Release

PHARBINEX-PE

Guaifenesin 400mg & Phenylephrine HCl 10mg

Expectorant & Nasal Decongestant

30 CAPLETS

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Drug Facts (continued)

Stop use and ask a doctor if nausea, dizziness or sleeplessness occurs ■ symptoms are accompanied by fever, rash or persistent headache ■ cough and congestion do not improve within 7 days or tend to recur

These could be signs of a serious illness.

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Directions

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- do not exceed 6 doses in 24 hours or as directed by doctor

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

Other information

- store at room temperature (15°-30°C)

Inactive ingredients croscarmellose sodium, hypromellose, lactose, magnesium stearate, malcodextrin, microcrystalline cellulose, mineral oil, povidone, silicon dioxide, sodium lauryl sulfate, stearic acid, titanium dioxide, triacetin

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Drug Facts (continued)

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PHARBINEX-PE			
guaifenesin 400mg and phenylephrine hcl 10mg tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-389
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	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	Score	2 pieces
Shape	CAPSULE (CAPSULE SHAPED TABLET)	Size	19mm
Flavor		Imprint Code	PH043
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-389-04	1 in 1 CARTON	05/01/2018	
1		30 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	05/01/2018	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(16103-389) , analysis(16103-389) , pack(16103-389) , label(16103-389)

