

**PHARBINEX-PE- guaifenesin 400mg and phenylephrine hcl 10mg tablet, coated**  
**Ulai Health 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.*

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**Drug Facts**

**Active ingredients (in each caplet)**

Guaifenesin 400mg

Phenylephrine HCl 10mg

**Purpose**

Expectorant

Nasal decongestant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- helps to make cough more productive
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

**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 the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to an enlarged prostate gland
- cough accompanied by too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**When using this product do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- nervousness, dizziness or sleeplessness occurs
- symptoms do not improve within 7 days, or are accompanied by a fever
- cough persists more than 7 days, tends to recur, or is accompanied by a fever, rash, persistent headache

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 the meals
- do not exceed 6 doses in 24 hours or as directed by a 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	ask a doctor

**Other information**

store at 20<sup>0</sup>- 25<sup>0</sup>C (68<sup>0</sup>-77<sup>0</sup>F)

**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 or comments?**

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by:

ULAI HEALTH LLC.

Alexandria, VA 22312

**PHARBEST**

**NDC 73057-389-04**

**Manufactured in the USA**

*Immediate Release*

**PHARBINEX-PE**


**Guaifenesin 400mg**

**Phenylephrine HCl 10mg**


**Expectorant &**

**Nasal Decongestant**

# 30 CAPLETS




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PHARBINEX-PE



Guaifenesin 400 mg &  
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30 CAPLETS

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Peel here for more drug facts



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Org. 05/19  
 Distributed by:  
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 Alexandria, VA 22312

**Drug Facts (continued)**

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**Questions or comments?**  
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STOP PEELING

<b>PHARBINEX-PE</b>			
guaifenesin 400mg and phenylephrine hcl 10mg tablet, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73057-389
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>	<b>Strength</b>		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
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	Size	19mm
Flavor		Imprint Code	PH043
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-389-04	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/18/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/18/2019	

**Labeler** - Ulai Health LLC (081181535)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(73057-389) , analysis(73057-389) , pack(73057-389) , label(73057-389)