

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.

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^o- 25^oC (68^o-77^oF)

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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Peel here for more drug facts

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Drug Facts (continued)

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STOP PEELING

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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73057-389 |
| 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 HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CROSCARMELOSE 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 | |

