**QUALITY CHOICE MUCUS RELIEF PE PE- guaifenesin/phenylephrine tablet**
**Chain Drug Marketing Association**

*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 ingredient -** (per tablet)

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

**Purpose**

Guaifenesin.....Expectorant

Phenylephrine HCl.....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
- drain bronchial tubes
- shrinks swollen membranes
- clears stuffy nose
- makes 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 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**.

**If pregnant or breast-feeding**, ask a health
professional before use.

**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 and over:
take 1 caplet every 4 hours as needed
■ children 6 to under 12 years:
take 1/2 caplet every 4 hours as needed
■ children under 6 years: consult a doctor
**Do not exceed 6 doses in a 24 hour period or as directed by a doctor.**

**Inactive ingredients**

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


# QUALITY CHOICE MUCUS RELIEF PE PE

guaifenesin/phenylephrine tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63868-752 |
| **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) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **MAGNESIUM SILICATE** (UNII: 9B9691B2N9) | |

| | |
|---|---|
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | RCCGPE;C27 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63868-752-50 | 1 in 1 CARTON | | |
| **1** | | 50 in 1 BOTTLE | | |

## Marketing Information

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

## Labeler - Chain Drug Marketing Association (011920774)

## Registrant - Reese Pharmaceutical Co (004172052)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Reese Pharmaceutical Co | | 004172052 | relabel(63868-752) , repack(63868-752) |

Revised: 4/2014 Chain Drug Marketing Association