

TOPCARE CHEST CONGESTION RELIEF- guaifenesin tablet
TOPCO ASSOCIATES 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 ingredient (per tablet)

Guaifenesin 400mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- helps make coughs more productive

Warnings

Ask doctor before use if you have

- persistent or chronic cough, such as occurs with smoking, asthma, bronchitis or emphysema
- cough is accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

- Symptoms are accompanied by fever, rash or persistent headache
- cough persists for more than 1 week or tends to recur

A persistent cough may be a sign of a serious condition.

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 immediately.

Directions

- **Adults and children 12 years of age and over:** take 1 tablet every 4 hours as needed
- **Children 6 to 10 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)

Inactive ingredients

magnesium stearate, microcrystalline cellulose. May also contain (colloidal) silicon dioxide, (co) povidone, dicalcium phosphate, maltodextrin, sodium starch glycolate, stearic acid.



TOPCARE CHEST CONGESTION RELIEF

guaifenesin tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-794 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | | Basis of Strength | Strength | |
|--|--|--|----------------------|--------------------|
| Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ) | | Guaifenesin | 400 mg | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | | |
| COPOVIDONE (UNII: D9C330MD8B) | | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | | |
| Product Characteristics | | | | |
| Color | white | Score | 2 pieces | |
| Shape | OVAL | Size | 17mm | |
| Flavor | | Imprint Code | PH063 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:36800-794-50 | 1 in 1 CARTON | 12/01/2013 | |
| 1 | | 50 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 | 08/01/2012 | | |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|------------------------|
| Pharbest | | 557054835 | manufacture(36800-794) |

Revised: 12/2022

TOPCO ASSOCIATES LLC