

ROBITUSSIN DIRECT CHEST CONGESTION- guaifenesin tablet, coated
Haleon US Holdings LLC

Drug Facts

Active ingredient (in each tablet)

Guaifenesin 400 mg

Purpose

Expectorant

Use

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

Warnings

Ask a doctor before use if you have

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

Stop use and ask a doctor if

cough persists more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache.

These could be signs 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 right away.

Directions

- take with a full glass of water
- do not take more than 6 tablets in 24 hours
- **do not take more than directed**

| | |
|--|--------------------------------|
| adults and children 12 years and over | take 1 tablet every 4 hours |
| children under 12 years | Do not use |

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

Call weekdays from 9 AM-5 PM EST at **1-800-245-1040**

Additional Information

Do not use if safety seal under cap printed with “Sealed for Your Protection” is broken or missing.

Lift Here for More Drug Facts

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PRINCIPAL DISPLAY PANEL

NEW

Robitussin

Chest Congestion

**Guaifenesin
(Expectorant)**

direct

Actual size

18

Tablets

L-0630-532-44-UPC_ORG Front Label



ROBITUSSIN DIRECT CHEST CONGESTION

guaifenesin tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0031-9303 |
| 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 |
|---|----------|
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | BLUE | Score | 2 pieces |
| Shape | ROUND | Size | 13mm |
| Flavor | | Imprint Code | 44;532 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0031-9303-01 | 18 in 1 BOTTLE; Type 0: Not a Combination Product | 07/15/2022 | 02/15/2025 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 07/15/2022 | 02/15/2025 |

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024

Haleon US Holdings LLC