

GUAIFENESIN - guaifenesin tablet, extended release
TOPCO ASSOCIATES LLC

Drug Facts

Active ingredient

(in each extended-release tablet)

Guaifenesin USP 1200 mg

Purpose

Expectorant

Uses

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

Warnings

Do not use

- for children under 12 years of age

Ask a doctor before use if you have

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

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or 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

- do not crush, chew, or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 extended-release tablet every 12 hours. Do not exceed 2 extended-release tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinised starch (maize)

Questions?

1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ITASCA, IL 60143 ©TOPCO ARHA0825
QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com

MADE IN INDIA

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg Blister Carton (56 (4 x14) Tablets)

Topcare®
health

NDC 76162-031-56

**COMPARE TO THE ACTIVE INGREDIENT
IN MAXIMUM STRENGTH MUCINEX®***

MAXIMUM STRENGTH

Mucus ER
GUAIFENESIN

EXTENDED-RELEASE TABLETS 1200 mg

GUAIFENESIN 1200 mg - EXPECTORANT
RELIEVES CHEST CONGESTION

**12
HOUR**

For Day or Night

- **Relieves Chest Congestion**
- **Thins & Loosens Mucus**

**56
EXTENDED-RELEASE TABLETS**

LEBG941P

Drug Facts

Active ingredient (in each extended-release tablet)
Guaifenesin USP 1200 mg

Purpose
Expectorant

Uses

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

Warnings

- Do not use
 - for children under 12 years of age
- Ask a doctor before use if you have
 - persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis, or emphysema
 - cough accompanied by too much phlegm (mucus)

Side effects and other information

- Cough lasts more than 7 days, comes back, or occurs with fever, rash, or 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. Use as directed. Get medical help or contact a Poison Control Center right away (1-800-422-1222).

Directions

- do not crush, chew, or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- swallow each extended-release tablet in its entirety
- swallow 12 extended-release tablets in 24 hours
- children under 12 years of age, do not use

Other information

- Store between 20° to 25° C (68° to 77° F)

Inactive ingredients
colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinized starch (maize).

Questions?
1-855-274-1122 (Monday - Friday 8:30 AM to 5:00 PM EST)

*This product is not manufactured or distributed by Rowlett Bancorser, distributor or Maxxim Strength Mucinex®.

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MADE IN INDIA

Scan here for more information or call 1-888-423-0139

QUALITY GUARANTEED



MAXIMUM STRENGTH Mucus ER

GUAIFENESIN
EXTENDED-RELEASE TABLETS 1200 mg
GUAIFENESIN 1200 mg - EXPECTORANT
RELIEVES CHEST CONGESTION



- Relieves Chest Congestion
- Thins & Loosens Mucus



MAXIMUM STRENGTH Mucus ER

GUAIFENESIN
EXTENDED-RELEASE TABLETS 1200 mg
GUAIFENESIN 1200 mg - EXPECTORANT
RELIEVES CHEST CONGESTION

NDC 76162-031-56

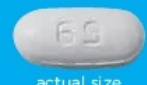
COMPARE TO THE ACTIVE INGREDIENT
IN MAXIMUM STRENGTH MUCINEX®*



For Day or Night

- Relieves Chest Congestion
- Thins & Loosens Mucus

56 EXTENDED-RELEASE TABLETS



actual size



MAXIMUM STRENGTH Mucus ER

GUAIFENESIN
EXTENDED-RELEASE TABLETS 1200 mg
GUAIFENESIN 1200 mg - EXPECTORANT
RELIEVES CHEST CONGESTION



- Relieves Chest Congestion
- Thins & Loosens Mucus

Transfer Extender. Do not use if caplet is open or if seal on blister is broken or missing.



- Relieves Chest Congestion
- Thins & Loosens Mucus



MAXIMUM STRENGTH Mucus ER

GUAIFENESIN
EXTENDED-RELEASE TABLETS 1200 mg
GUAIFENESIN 1200 mg - EXPECTORANT
RELIEVES CHEST CONGESTION



P1062663

Unmarked Zone
(do not use for printing)
83 x 115 mm

GUAIFENESIN
guaifenesin tablet, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76162-031 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 1200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2) | |
| HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK) | |
| MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y) | |
| POVIDONE K90 (UNII: RDH86HJV5Z) | |
| POVIDONE K25 (UNII: K0KQV10C35) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|----------|
| Color | WHITE (white to off-white) | Score | no score |
| Shape | OVAL | Size | 21mm |
| Flavor | | Imprint Code | L;69 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76162-031-56 | 4 in 1 CARTON | 04/22/2026 | |
| 1 | | 14 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| ANDA | ANDA210453 | 04/22/2026 | |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED | | 650918514 | ANALYSIS(76162-031) , MANUFACTURE(76162-031) |

Revised: 4/2026

TOPCO ASSOCIATES LLC