MUCUS RELIEF MAXIMUM STRENGTH- guaifenesin tablet TOP CARE (Topco Associates LLC)

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 1200 mg

Purpose

Expectorant

Uses

Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and makes 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 accopanied 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 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 tablet every 12 hours. Do not exceed 2 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

carbomer, colloidal silicon dioxide, FD&C blue #1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO MAXIMUM STRENGTH MUCINEX® ACTIVE INGREDIENT*

MAXIMUM STRENGTH

Mucus Relief

EXPECTORANT - GUAIFENESIN 1200 mg

- 12-Hour Relief
- Relieves Chest Congestion
- Thins & Loosens Mucus

EXTENDED-RELEASE TABLETS

*This product is not manufactured or distributed by Reckitt Benckiser LLC, distributor of Maximum Strength Mucinex ${\mathbb R}$.

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY TOPCO ASSOCIATES LLC,

ELK GROVE VILLAGE, IL 60007

www.topcarebrand.com

Package Label



TOPCARE HEALTH Maximum Strength Mucus Relief

MUCUS RELIEF MAXIMUM STRENGTH quaifenesin tablet **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:36800-932 **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) **GUAIFENES IN** 1200 mg **Inactive Ingredients Ingredient Name** Strength SILICON DIOXIDE (UNII: ETJ7Z6XBU4) MAGNESIUM STEARATE (UNII: 70097M6I30) CARBOMER 934 (UNII: Z135WT9208)

| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
|--|--|
| POVIDONE (UNII: FZ989GH94E) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| TALC (UNII: 7SEV7J4R1U) | |

| Product Characteristics | | | | | | |
|-------------------------|------|--------------|----------|--|--|--|
| Color | blue | Score | no score | | | |
| Shape | OVAL | Size | 22mm | | | |
| Flavor | | Imprint Code | AN037 | | | |
| Contains | | | | | | |

| P | Packaging | | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:36800-932- 14 | 14 in 1 CARTON | 03/31/2019 | | | |
| 1 | | 1 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 | ANDA207342 | 03/31/2019 | | | |
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Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 11/2022 TOP CARE (Topco Associates LLC)