**12 HOUR MUCUS RELIEF- guaifenesin tablet, extended release**
**CHAIN DRUG MARKETING ASSOCIATION INC**

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**1203A-QCH-2021-1108**

***Drug Facts***

**Active ingredient (in each extended-release tablet)**

Guaifenesin 600 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 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 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours.

■ children under 12 years of age: do not use

**Other information**

■ store between 20-25ºC (68-77ºF)

■ retain carton for complete product information and warnings

**Inactive ingredients**

carbomer homopolymer type B, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

**PRINCIPAL DISPLAY PANEL**

QUALITY CHOICE®

NDC 63868-149-20

†Compare to the Active Ingredient in MUCINEX®

12 Hour

Mucus Relief

Expectorant

Guaifenesin Extended-Release Tablets, 600 mg

• Relieves Chest Congestion

• Thins & Loosens Mucus

• Immediate and Extended Release

Actual Size

20 EXTENDED-RELEASE TABLETS


# 12 HOUR MUCUS RELIEF

guaifenesin tablet, extended release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:63868-149 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 600 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)** (UNII: Z135WT9208) | |
| **HYPROMELLOSE 2910 (15 MPA.S)** (UNII: 36SFW2JZ0W) | |
| **SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | no score |
| **Shape** | OVAL | **Size** | 16mm |
| **Flavor** | | **Imprint Code** | G;600 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:63868-149-20 | 2 in 1 CARTON | 09/17/2021 | |
| **1** | | 10 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 | ANDA213420 | 09/17/2021 | |

## Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 11/2021 CHAIN DRUG MARKETING ASSOCIATION INC