# MUCUS RELIEF DM- guaifenesin dextromethorphan hbr tablet, extended release

**QUALITY CHOICE (Chain Drug Marketing Association)** 

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## **Drug Facts**

## Active ingredients (in each extended-release tablet)

Dextromethorphan HBr 60 mg
Guaifenesin 1200 mg

## **Purpose**

Cough Suppressant

Expectorant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - · the impulse to cough to help you get to sleep

# Warnings

#### Do not use

- for children under12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

# 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)

# When using this product,

do not use more than directed.

# 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 regards for timing of meals
- adults and children 12 years of age and older: 1 tablet every 12 hours; not more than 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, D&Cyellow #10 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, talc

## Questions or comments?

Call 1-800-935-2362 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

\*Compare to the Active Ingredients in Maximum Strength Mucinex® DM

Maximum Strength

#### **Mucus Relief DM**

Guaifenesin 1200 mg

& Dextromethorphan HBr 60 mg

**Extended-Release Tablets** 

Expectorant & Cough suppressant

- 12-hour relief
- Controls Cough
- Thins and loosens mucus

#### Extended-Release Tablets

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, distributor of Maximum Strength Mucinex® DM

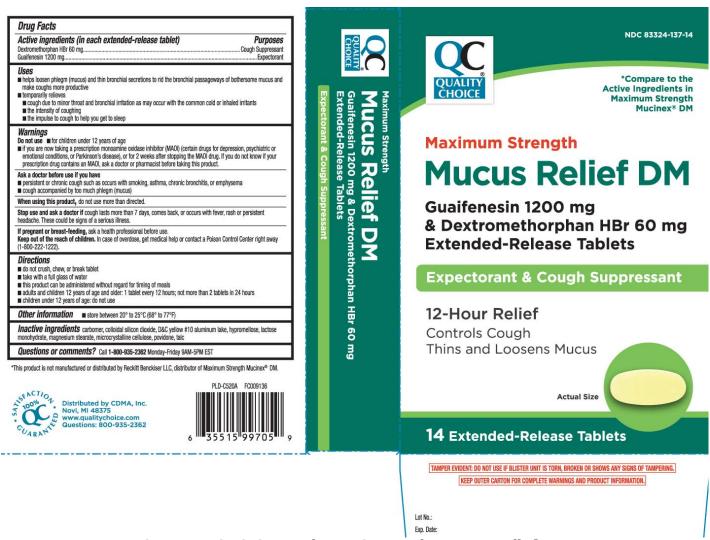
TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CDMA, Inc.

Novi, MI 48375

#### Package Label



#### **QUALITY CHOICE Maximum Strength Mucus Relief DM**

#### **MUCUS RELIEF DM**

quaifenesin dextromethorphan hbr tablet, extended release

| Product Information     |                |                    |                              |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:83324-137(NDC:65162-039) |
| Route of Administration | ORAL           |                    |                              |

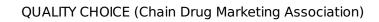
| Active Ingredient/Active Moiety  |                                  |          |  |
|--|----------------------------------|----------|--|
| Ingredient Name  | Basis of Strength                | Strength |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 60 mg    |  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 1200 mg  |  |

| Inactive Ingredients                           |          |  |  |
|--|----------|--|--|
| Ingredient Name                                | Strength |  |  |
| <b>CARBOMER 934</b> (UNII: Z135WT9208)         |          |  |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)             |          |  |  |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)           |          |  |  |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)   |          |  |  |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)         |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)          |          |  |  |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) |          |  |  |
| POVIDONE (UNII: FZ989GH94E)                    |          |  |  |
| TALC (UNII: 7SEV7J4R1U)                        |          |  |  |

| Product Characteristics |                       |              |          |
|-------------------------|-----------------------|--------------|----------|
| Color                   | yellow (light yellow) | Score        | no score |
| Shape                   | OVAL                  | Size         | 22mm     |
| Flavor                  |                       | Imprint Code | AN039    |
| Contains                |                       |              |          |

| P | Packaging            |  |                         |                       |  |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code            | Package Description                                    | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:83324-137-<br>14 | 14 in 1 CARTON   | 07/31/2024              |                       |  |
| 1 |                      | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA                  | ANDA209692                                  | 07/31/2024              |                       |
|                       |   |                         |                       |



Revised: 5/2024