# GUAIFENESIN AND DEXTROMETHORPHAN HBR - guaifenesin and dextromethorphan hbr tablet, extended release Target Corporation

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#### **Drug Facts**

## Active ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 60 mg Guaifenesin USP 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 under 12 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 (1-800-222-1222) right away.

#### **Directions**

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years 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 at 20° to 25°C (68° to 77°F)

# Inactive ingredients

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

#### Questions?

call **1-855-274-4122** You may also report side effects to this phone number.

Distributed by Target Corporation

Minneapolis, MN 55403

#### Made in India

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# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg (14 Tablet Bottle)

**Maximum Strength** 

Mucus Relief DM

Guaifenesin and Dextromethorphan HBr Extended-release Tablets 1200 mg/60 mg

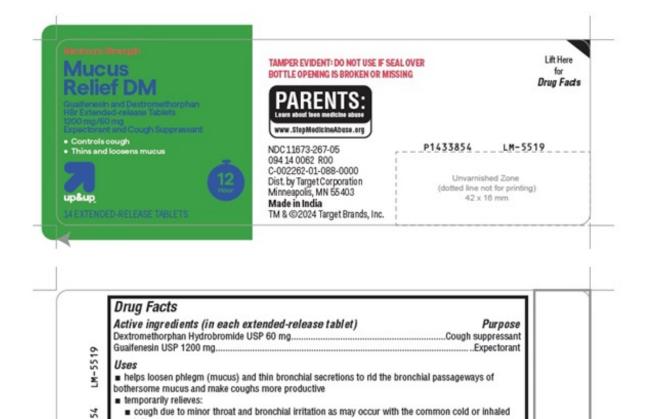
**Expectorant and Cough Suppressant** 

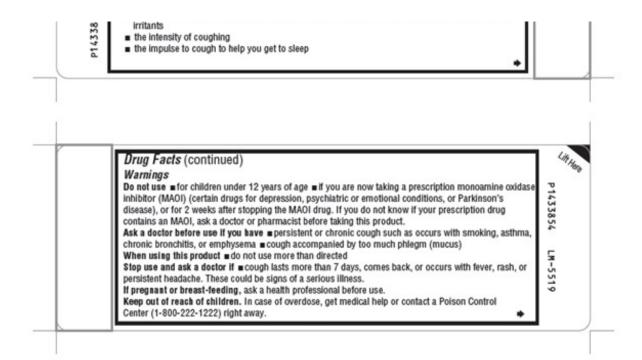
- Controls cough
- Thins and loosens mucus

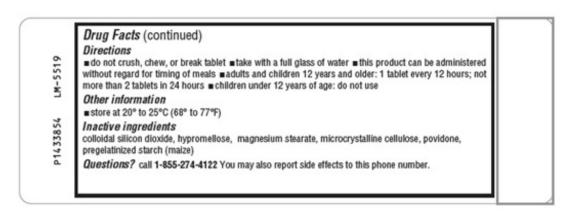
up&up™

12 Hour

#### 14 EXTENDED-RELEASE TABLETS









Compare to the active ingredients of Maximum Strength Mucinex® DM\*

**Maximum Strength** 

NDC 11673-267-05

Mucus Relief DM

Guaifenesin and Dextromethorphan HBr Extended-release Tablets 1200 mg/60 mg

**Expectorant and Cough Suppressant** 

- Controls cough
- Thins and loosens mucus

up&up™

12 Hour

Actual Size **14 Tablets** 

14 EXTENDED-RELEASE TABLETS



#### **GUAIFENESIN AND DEXTROMETHORPHAN HBR**

guaifenesin and dextromethorphan hbr tablet, extended release

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11673-267

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength                | Strength |
|--|----------------------------------|----------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN                      | 1200 mg  |
| ,  | DEXTROMETHORPHAN<br>HYDROBROMIDE | 60 mg    |

#### **Inactive Ingredients**

| mactive mgreateries                           |          |  |
|---|----------|--|
| Ingredient Name                               | Strength |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)            |          |  |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)  |          |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)         |          |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) |          |  |
| 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         | 22mm     |
| Flavor                  |                            | Imprint Code | X;63     |
| Contains                |                            |              |          |

| P | Packaging            |   |                         |                       |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code            | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:11673-267-<br>05 | 1 in 1 CARTON                                     | 07/04/2024              |                       |
| 1 |                      | 14 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |
| 2 | NDC:11673-267-<br>57 | 1 in 1 CARTON                                     | 07/04/2024              |                       |
| 2 |                      | 28 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |
| 3 | NDC:11673-267-<br>60 | 1 in 1 CARTON                                     | 07/04/2024              |                       |
| 3 |                      | 42 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |

| Marketing Information                                       |            |                         |                       |
|---|------------|-------------------------|-----------------------|
| Marketing Application Number or Monograph Category Citation |            | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA  | ANDA206941 | 07/04/2024              |                       |
|   |            |                         |                       |

# Labeler - Target Corporation (006961700)

# Registrant - Aurohealth LLC (078728447)

| Establishment            |         |           |   |  |
|--------------------------|---------|-----------|---|--|
| Name                     | Address | ID/FEI    | Business Operations                         |  |
| Aurobindo Pharma Limited |         | 650381903 | ANALYSIS(11673-267), MANUFACTURE(11673-267) |  |

Revised: 7/2024 Target Corporation