

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

**Ahold U.S.A., Inc,**

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## ***Drug Facts***

### ***Active Ingredients***

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

Dextromethorphan Hydrobromide USP 30 mg

Guaifenesin USP 600 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 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

## ***Other information***

- tamper evident: do not use if seal over bottle opening is broken or missing
- 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 **1-877-846-9949** You may also report side effects to this phone number.

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg (20 Tablet**

Bottle)

NDC 60000-058-67

MUCUS RELIEF DM

Guaifenesin 600 mg / Dextromethorphan HBr 30 mg

Extended-Release Tablets

Expectorant/Cough Suppressant

Controls Cough

Thins and Loosens Mucus

20 EXTENDED-RELEASE TABLETS

Top Layer Printing side

The image shows the top layer printing side of the bottle label. It features the CAREone logo in the top left corner. To the right of the logo is the NDC number 60000-058-67. Below the logo, the product name 'MUCUS RELIEF DM' is printed in large, bold letters. Underneath the product name, the active ingredients and their strengths are listed: 'Guaifenesin 600 mg / Dextromethorphan HBr 30 mg'. This is followed by 'Extended-Release Tablets' and 'Expectorant/Cough Suppressant'. A blue box contains the text 'Controls Cough' and 'Thins and Loosens Mucus'. To the right of this box is a circular icon with '12h' inside, indicating the extended-release duration. At the bottom of the label, it says '20 EXTENDED-RELEASE TABLETS'. On the right side of the label, there is a section for 'DISTRIBUTED BY: FOODHOLD, U.S.A., LLC, LANDOVER, MD 20785, 1-877-646-9949, © 2017 S&S Brands, LLC'. Below this is a quality guarantee statement: 'Quality guaranteed or your money back. www.Care1.info'. Further down, it says 'Made in India' and 'M.L.No.: 22/MNAR/2009FR LM-2530'. At the bottom right, there are fields for 'Lot:' and 'Exp:'.

61.33

Top Layer Adhesive side

The image shows the top layer adhesive side of the bottle label. It features a pink vertical bar on the right side labeled 'Gluing Area'. The main content is enclosed in a black border and includes the following text: 'Drug Facts', 'Active ingredients (in each extended-release tablet)', 'Purpose', 'Uses', and a list of bullet points describing the product's benefits and uses. The text is as follows: 'Drug Facts', 'Active ingredients (in each extended-release tablet)', 'Purpose', 'Dextromethorphan Hydrobromide USP 30 mg.....Cough suppressant', 'Guaifenesin USP 600 mg.....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'. On the left side of the label, there is a vertical label 'LM-2530' and '082C-WT'. On the right side, there is a vertical label 'Gluing Area'.

2nd Layer Printing side

The image shows the 2nd layer printing side of the bottle label. It features a pink vertical bar on the left side labeled 'Gluing Area'. The main content is enclosed in a black border and includes the following text: 'Drugs Facts (Continued)', 'Warnings', and a list of bullet points describing the product's warnings and precautions. The text is as follows: 'Drugs Facts (Continued)', '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.' On the right side of the label, there is a vertical label 'LM-2530' and 'Lift Here'.

## 2nd Layer Adhesive side

0832-N1

**Drugs Facts (Continued)**  
**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 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours ■ children under 12 years of age: do not use

**Other information**  
■ tamper evident: do not use if seal over bottle opening is broken or missing  
■ 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 1-877-846-9949 You may also report side effects to this phone number.

Gluing Area

## Base Layer

Gluing Area

**CAREone**® NDC 60000-058-67

**MUCUS RELIEF DM**

Guaifenesin 600 mg / Dextromethorphan HBr 30 mg  
Extended-Release Tablets  
Expectorant/Cough Suppressant

Controls Cough  
Thins and Loosens Mucus

12h

20 EXTENDED-RELEASE TABLETS

DISTRIBUTED BY:  
FOODHOLD, U.S.A., LLC  
LANDOVER, MD 20785  
1-877-846-9949  
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Quality guaranteed or your money back.  
www.Care1.info

**PARENTS:**  
Learn about your medicine online  
www.StayMedicineAbese.org

UM-2530

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg (20 Tablet Carton Label)

NDC 60000-058-67

**CARE ONE®**

compare to the active ingredient in  
**Mucinex® DM\***

**MUCUS**

**RELIEF DM**

**Guaifenesin 600 mg/**

**Dextromethorphan HBr 30 mg**

**Extended-Release Tablets**

**Expectorant/Cough Suppressant**

Controls Cough

Thins and Loosens Mucus

**20**

**EXTENDED RELEASE  
TABLETS**



## MUCUS RELIEF DM

guaifenesin and dextromethorphan hbr tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60000-058
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>POVIDONE K25</b> (UNII: K0KQV10C35)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

## Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	X;62
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60000-058-67	1 in 1 CARTON	03/17/2017	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206941	03/17/2017	

**Labeler** - Ahold U.S.A., Inc, (188910863)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(60000-058) , MANUFACTURE(60000-058)

Revised: 12/2023

Ahold U.S.A., Inc,