# $\mbox{MUCUS RELIEF DM}$ - 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

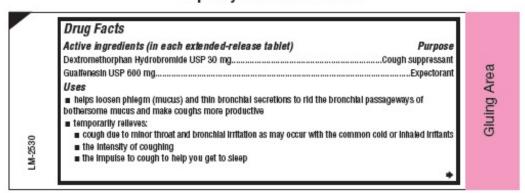
Controls Cough
Thins and Loosens Mucus
20 EXTENDED-RELEASE TABLETS

#### Top Layer Printing side



61.33

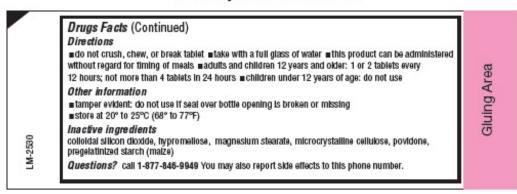
#### Top Layer Adhesive side



#### 2nd Layer Printing side

#### LAHER 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 Gluing Area 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 acough accompanied by too much phiegm (mucus) When using this product a do not use more than directed Stop use and ask a doctor if a cough lasts more than 7 days, comes back, or occurs with fever, rash, or LM-2530 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.

#### 2nd Layer Adhesive side



#### Base Layer



# 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 Product Type HUMAN OTC DRUG Item Code (Source) NDC:60000-058 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (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			
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	16mm
Flavor		Imprint Code	X;62
Contains			

Packaging				
#	tem 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,