

**GUAIFENESIN AND DEXTROMETHORPHAN HBR - guaifenesin and dextromethorphan hbr tablet, extended release**  
**Aurohealth LLC**

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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 carton is open or if printed seal on blister 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 **1-855-274-4122** You may also report side effects to this phone number.

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

NDC 58602-824-67

Primary Health

COMPARE TO Mucinex® DM

Active ingredients\*

Mucus Relief DM

Guaifenesin and

Dextromethorphan HBr

Extended-Release

Tablets 600 mg/30 mg

## EXPECTORANT AND COUGH SUPPRESSANT

- Controls Cough
- Thins and Loosens Mucus

12 Hour

20 Tablets

Extended-Release Tablets

LM-3162

20 Tablets  
Extended-Release Tablets

PrimaryHealth  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablets 600 mg/30 mg

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EXPECTORANT AND  
COUGH SUPPRESSANT

- Controls Cough
- Thins and Loosens Mucus

12-HOUR

62

20 Tablets  
Extended-Release Tablets

Lot: \_\_\_\_\_  
Exp: \_\_\_\_\_

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

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Guaifenesin USP 600 mg	Expectorant

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**Mucus Relief DM**  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablets 600 mg/30 mg

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

Distributed by:  
AURORHEALTH LLC  
2572 Brunswick Pike,  
Lawrenceville, NJ 08648  
Made in India  
Code: 1SDRUGS/22/2019

**PARENTS:**  
Keep this and all medicines out of the reach of children.  
www.topmedfactors.com

5860218246719

# GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-824
<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: 9D2RT19KYH) (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:58602-824-67	2 in 1 CARTON	03/17/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-824-08	4 in 1 CARTON	03/17/2017	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

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

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-824) , MANUFACTURE(58602-824)

Revised: 2/2024

Aurohealth LLC