

**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 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***

- 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.

Distributed by:  
**AUROHEALTH LLC**  
2572, Brunswick Pike  
Lawrenceville, NJ 08648

Made in India

Code: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg 14 (2 x 7) Tablets Carton Label**

**Healthy Living™**

**NDC 58602-849-65**

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

**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**

**12  
HOUR**

**63  
14 (2 x 7) Extended-release Tablets**



**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg (60 Tablet Container Label)**

**Healthy Living™**

**NDC 58602-849-15**

**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**

**12  
HOUR**

**63**

# 60 Extended-release Tablets

## Top Layer Printing side



N 3 58602 84915 3

 **Healthy Living™** NDC 58602-849-15

**MAXIMUM STRENGTH**

### Mucus Relief DM

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

**EXPECTORANT AND  
COUGH SUPPRESSANT**

- Controls Cough
- Thins and Loosens Mucus

12  
HOUR

**60 Extended-release Tablets**

**Drug Facts**

**Active ingredients (in each extended-release tablet)** Purpose  
Dextromethorphan Hydrobromide USP 60 mg.....Cough suppressant  
Guafenesin USP 1200 mg.....Expectorant

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**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

LM-4209  
P1426412

Drug Facts  
Lift Here for

## Top Layer Adhesive side

P1426412 LM-4209

**Drugs Facts (Continued)**

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
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  - the intensity of coughing
  - the impulse to cough to help you get to sleep

**Warnings**

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- 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

Gluing Area

## Base Layer

Gluing Area

**Drugs Facts (Continued)**

headache. These could be signs of a serious illness.

**If pregnant or breast-feeding**, ask a health professional before use.

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**Directions**

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

P1426412 LM-4209

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg (60 Tablet  
Container Carton)**

**Healthy Living™**

**NDC 58602-849-15**

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

**MAXIMUM STRENGTH**

**Mucus Relief DM**

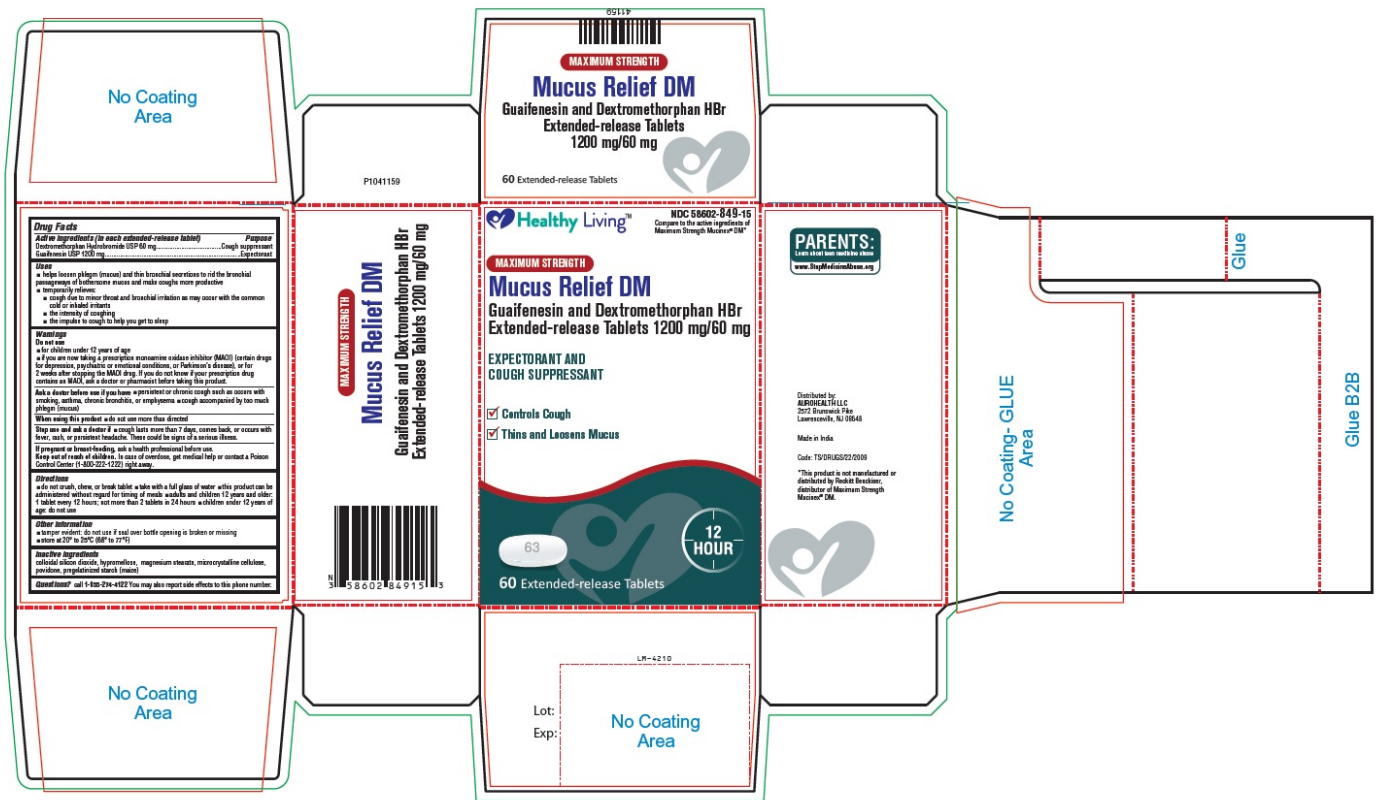
**Guaifenesin and Dextromethorphan HBr  
Extended-release Tablets 1200 mg/60 mg**

**EXPECTORANT AND  
COUGH SUPPRESSANT**

**Controls Cough  
Thins and Loosens Mucus**

**12  
HOUR**

**63  
60 Extended-release Tablets**



# 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:58602-849
<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	1200 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 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>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	X;63
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-849-65	2 in 1 CARTON	05/16/2020	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-849-11	8 in 1 CARTON	08/13/2020	
2		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-849-15	1 in 1 CARTON	08/13/2020	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-849-57	1 in 1 CARTON	09/08/2020	
4		28 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-849-64	1 in 1 CARTON	02/24/2021	
5		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206941	05/16/2020	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-849) , MANUFACTURE(58602-849)