

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

-----  
***Drug Facts***

***Active ingredients***

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

Dextromethorphan Hydrobromide USP 60 mg  
Guaifenesin USP 1200 mg

***Purposes***

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 extended-release 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 extended-release tablet every 12 hours; not more than 2 extended-release 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**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 60 mg/1200 mg (42 Tablet Carton Label)**

**NDC 58602-825-06**

**Primary Health**

**COMPARE TO** Maximum Strength  
Mucinex<sup>®</sup> DM Active ingredients\*

**MAXIMUM STRENGTH**

**Mucus Relief DM**

**Dextromethorphan HBr and**

**Guaifenesin Extended-release Tablets**

**60 mg/1200 mg**

**Dextromethorphan HBr** 60 mg- Cough Suppressant

**Guaifenesin** 1200 mg - Expectorant

**RELIEVES COUGH & CHEST CONGESTION**

✓ **Controls Cough**

✓ **Thins & Loosens Mucus**

ACTUAL SIZE

**12**

**HOUR**

**42 Tablets**

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:58602-825
<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: 9D2RTI9KYH) (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: 70097M6I3O)	
<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:58602-825-65	2 in 1 CARTON	03/17/2017	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-825-06	6 in 1 CARTON	03/17/2017	
2		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	03/17/2017	

**Labeler** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-825) , MANUFACTURE(58602-825)

Revised: 4/2025

Aurohealth LLC