

# **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

Guaiifenesin 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.

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

**HealthyLiving**

**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**



## GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaiifenesin and dextromethorphan hbr tablet, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-849
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 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	22mm
Flavor		Imprint Code	X;63
Contains			

## 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		

## Marketing Information

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

**Labeler** - Eurohealth LLC (078728447)

## Establishment

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