

**GUAIFENESIN AND DEXTROMETHORPHAN HBR- guaifenesin and dextromethorphan hbr tablet, extended release**  
**OHM LABORATORIES INC**

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**Guaifenesin and Dextromethorphan HBr**

***Drug Facts***

<b><i>Active ingredients (in each extended-release tablet)</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr 60 mg	Cough suppressant
Guaifenesin 1200 mg	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 right away (1-

800-222-1222).

### **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 between 20-25°C (68-77°F)

### **Inactive ingredients**

carbomer homopolymer, colloidal silicon dioxide, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), stearic acid

### **Questions?**

**(1-800-406-7984)**

You may also report side effects to this phone number.

Distributed by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

### **PRINCIPAL DISPLAY PANEL - 28 Tablet Blister Pack Carton**

†Compare To  
the active ingredients of  
Maximum Strength  
Mucinex<sup>®</sup> DM

NDC 51660-110-86

Ohm Laboratories Inc.

Maximum Strength

Guaifenesin 1200 mg  
& Dextromethorphan HBr 60 mg  
Extended-Release Tablets

Expectorant & Cough Suppressant

12 Hour

- Controls Cough
- Thins and Loosens Mucus

- Immediate and Extended Release

## 28 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:51660-110
<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>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01ZNK31)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white (off-white)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	053
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-110-54	1 in 1 CARTON	07/01/2021	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-110-86	2 in 1 CARTON	07/01/2021	
2		14 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	ANDA214781	07/01/2021	

**Labeler** - OHM LABORATORIES INC (184769029)

**Registrant** - SUN PHARMACEUTICAL INDUSTRIES, INC. (146974886)

### Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650456002	manufacture(51660-110)