

**GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide tablet, extended release**  
**CVS PHARMACY, INC**

-----  
**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: CVS Pharmacy, Inc.  
One CVS Drive, Woonsocket, RI 02895

### **PRINCIPAL DISPLAY PANEL - 70 Tablet Blister Pack Carton**

VALUE SIZE

70

TABLETS

CVSHealth®

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

NDC 51316-600-70

MAXIMUM STRENGTH

Mucus DM

Extended-

Release

12

HOUR

# GUAIFENESIN & DEXTROMETHORPHAN HYDROBROMIDE EXTENDED-RELEASE TABLETS, 1200 mg/60 mg

## EXPECTORANT/COUGH SUPPRESSANT

- Controls cough
- Thins & loosens mucus
- Immediate & extended-release

## 70 EXTENDED-RELEASE TABLETS



# GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide tablet, extended release

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51316-600

<b>Route of Administration</b>	Oral
--------------------------------	------

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	60 mg

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<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: HHT01Z NK31)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>Product Characteristics</b>			
<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>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-600-70	5 in 1 CARTON	04/19/2022	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214781	04/19/2022	

**Labeler** - CVS PHARMACY, INC (062312574)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Ohm Laboratories Inc.		184769029	MANUFACTURE(51316-600)

Revised: 4/2022

CVS PHARMACY, INC