

**GUAIFENESIN DM- guaifenesin and dextromethorphan syrup**  
**Cardinal Health 107, LLC**

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**GUAIFENESIN DM**

*Non-Narcotic, Alcohol Free*  
*Expectorant/Cough Suppressant*

**DESCRIPTION**

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Each 5 mL (1 teaspoonful)	
contains:	
Guaifenesin	100 mg
Dextromethorphan Hydrobromide	10 mg

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*Inactive Ingredients:* Citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

*Sodium Content:* 4 mg/5 mL

**USES**

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

**WARNINGS**

**Do not use** 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**

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

- you are hypersensitive to any of the ingredients.

**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.

**Professional Note:** Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

**DIRECTIONS:** Follow dosage below or use as directed by a physician.

- do not take more than 6 doses in any 24-hour period.

<b>age</b>	<b>dose</b>
adults and children 12 years and over	10 mL (2 teaspoonfuls) every 4 hours
children 6 years to under 12 years	5 mL (1 teaspoonful) every 4 hours
children 2 years to under 6 years	2.5 mL (1/2 teaspoonful) every 4 hours
children under 2 years	ask a doctor

**HOW SUPPLIED:** Guaifenesin Syrup and Dextromethorphan is a red, cherry flavored syrup supplied in the following oral dosage forms:

Overbagged with 5 cups per bag, NDC 55154-5785-5

**STORAGE:** Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F) [See USP]. Protect from light.

#### **MANUFACTURED BY**

##### **Pharmaceutical Associates, Inc.**

Greenville, SC 29605  
www.paipharma.com

##### **Distributed By:**

##### **Cardinal Health**

Dublin, OH 43017

L54670891223


**R11/16**

#### **Principal Display Panel**

Guaifenesin Syrup and Dextromethorphan

100 mg/10 mg per 5 mL

5 x 10 mL Cups



**R111**

**NDC 55154-5785-5**

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**GUAIFENESIN SYRUP AND  
DEXTROMETHORPHAN**  
**100 mg/10 mg per 5 mL**

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**5 CUPS**

**Delivers 5 mL**

See product insert for prescribing information, precautions and warnings.

**STORAGE:** Store at 20° to 25° C (68° to 77° F)  
[See USP Controlled Room Temperature]

**WARNING:** This Unit Dose package is not child resistant and is Intended for Institutional Use Only.  
Keep this and all drugs out of the reach of children.

**PHARMACEUTICAL ASSOCIATES, INC.**  
201 Delaware Street  
GREENVILLE, SC 29605  
(800) 845-8210  
www.paipharma.com  
DURA-DOSE®

Distributed by Cardinal Health  
Dublin, OH 43017  
L54670891223

Lot:            Exp:

## **GUAIFENESIN DM**

guaifenesin and dextromethorphan syrup

### **Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:55154-5785(NDC:0121-0638)

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>DEXTROMETHORPHAN</b> (UNII: 7355X3ROTS) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-5785-5	5 in 1 BAG	07/01/1992	
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/1992	

**Labeler** - Cardinal Health 107, LLC (118546603)

