

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

GUAIFENESIN DM

Non-Narcotic, Alcohol Free
Expectorant/Cough Suppressant

DESCRIPTION

Each 5 mL (1 teaspoonful) contains:

Guaifenesin	100 mg
Dextromethorphan Hydrobromide	10 mg

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.

age	dose
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 x 5 mL unit dose cups in each bag, NDC 55154-5785-5

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.

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

L54670891225

R11/16

Principal Display Panel

NDC 55154-5785-5

GUAIFENESIN SYRUP AND

DEXTROMETHORPHAN

100 mg/10 mg per 5 mL

5 CUPS



R111

NDC 55154-5785-5

GUAIFENESIN SYRUP AND

DEXTROMETHORPHAN

100 mg/10 mg per 5 mL

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.

PAI Pharma

GREENVILLE, SC 29605

1-800-845-8210

www.paipharma.com

DURA-DOSE®

Distributed by Cardinal Health

Dublin, OH 43017

L54670891225

Lot:

Exp:

GUAIFENESIN DM

guaifenesin and dextromethorphan syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-5785(NDC:0121-0638)
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Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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100 mg

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
DEXTROMETHORPHAN (UNII: 7355X3ROTS) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

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)