

GUAIFENESIN DM- guaifenesin and dextromethorphan syrup
American Health Packaging

GUAIFENESIN and DEXTROMETHORPHAN SYRUP
Drug Facts

Active ingredient (in each 5 mL Cup)

Guaifenesin 100 mg
Dextromethorphan Hydrobromide 10 mg

Purpose

Expectorant
Cough Suppressant

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.

Directions

Follow dosage below or use as directed by a physician.

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

Age (yr)	Dose (mL)
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

Other Information

- **Each 5 mL contains:** sodium 4 mg
- Store at controlled room temperature between 20° to 25°C (68° to 77°F) [see USP]. Protect from light.
- **DO NOT USE IF SEAL IS BROKEN.**
- Guaifenesin Syrup and Dextromethorphan is a red, cherry flavored syrup and is available in the following dosage forms:
 - 5 mL unit-dose cups: 100 cups (10 x 10) NDC 60687-817-17
 - 10 mL unit-dose cups: 100 cups (10 x 10) NDC 60687-828-56

Inactive Ingredients

citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

Questions or comments?

Call 1-800-845-8210

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).

Distributed by:

American Health Packaging

Columbus, OH 43217

R0324

Package/Label Principal Display Panel - Label

Case NDC 60687-817-17/Cup NDC 60687-817-40

**GUAIFENESIN and
DEXTROMETHORPHAN
SYRUP**

Expectorant/Cough Suppressant

100 mg/10 mg per 5 mL

Non-Narcotic, Alcohol Free

Cherry Flavor

Usual Dosage: See attached Drug Facts.

Store at 20° to 25°C (68° to 77°F) [See USP]

Protect from light.

FOR INSTITUTIONAL USE ONLY

T0638C050324

R03/24

Case NDC 60687-817-17/Cup NDC 60687-817-40

**GUAIFENESIN and
DEXTROMETHORPHAN
SYRUP**

Expectorant/Cough Suppressant

100 mg/10 mg per 5 mL

Non-Narcotic, Alcohol Free

Cherry Flavor

Usual Dosage: See attached Drug Facts.

Store at 20° to 25°C (68° to 77°F) [See USP]

Protect from light.

FOR INSTITUTIONAL USE ONLY

T0638C050324

R03/24

Package/Label Principal Display Panel - Cup Lid - 100 mg/10 mg per 5 mL



NDC 60687- **817**-40

**Guaifenesin and
Dextromethorphan Syrup**

Expectorant/cough Suppressant

100 mg/10 mg per 5 mL

Delivers 5 mL

Protect from light

See package Drug Facts insert for full
prescribing information and storage

For Institutional Use Only.

American Health Packaging
Columbus, OH 43217

F0638C050224

GUAIFENESIN DM

guaifenesin and dextromethorphan syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60687-817
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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: 059QF0KOOR)	
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:60687-817-17	10 in 1 CASE	08/04/2024	
1	NDC:60687-817-46	10 in 1 TRAY		
1	NDC:60687-817-40	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	08/04/2024	

Labeler - American Health Packaging (929561009)