GUAIFENESIN- guaifenesin solution
American Health Packaging

Guaifenesin Oral Solution USP
Drug Facts

Expectorant
SUGAR FREE / ALCOHOL FREE

Active ingredient

- **(in each 5 mL Cup)** Guaifenesin 100 mg
- **(in each 10 mL Cup)** Guaifenesin 200 mg
- **(in each 15 mL Cup)** Guaifenesin 300 mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

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 to 20 ml (2 to 4 teaspoonfuls) every 4 hours
children 6 years to under 12 years	5 to 10 ml (1 to 2 teaspoonfuls) every 4 hours
children 2 years to under 6 years	2.5 to 5 ml (1 /2 to 1 teaspoonful) every 4 hours
children under 2 years	consult a physician

Other Information

- **Each 5 ml contains:** sodium 4 mg.
- **Each 10 ml contains:** sodium 8 mg.
- **Each 15 ml contains:** sodium 12 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 Oral Solution is a red, raspberry flavored solution and is available in the following dosage forms:
  5 ml unit-dose cups: 100 cups (10 x 10) NDC 60687-852-17
  10 ml unit-dose cups: 100 cups (10 x 10) NDC 60687-863-56
  15 ml unit-dose cups: 100 cups (10 x 10) NDC 60687-874-16

Inactive Ingredients

Acesulfame K, citric acid, FD&C Green No. 3, FD&C Red No. 40, flavoring, hydroxyethylcellulose, purified water, sodium benzoate, and sodium citrate.

Questions or comments?

Call 1-800-845-8210

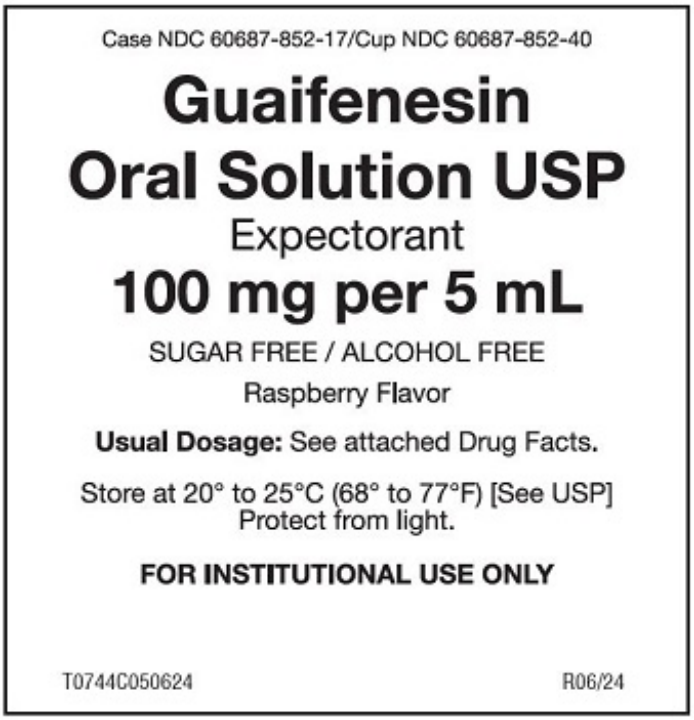
Generic Section

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

R0624

Package/Label Principal Display Panel – 100 mg per 5 mL – Label



Case NDC 60687- **852**-17/Cup NDC 60687- **852**-40

Guaifenesin
Oral Solution USP
Expectorant

100 mg per 5 ml

SUGAR FREE / ALCOHOL FREE
Raspberry Flavor

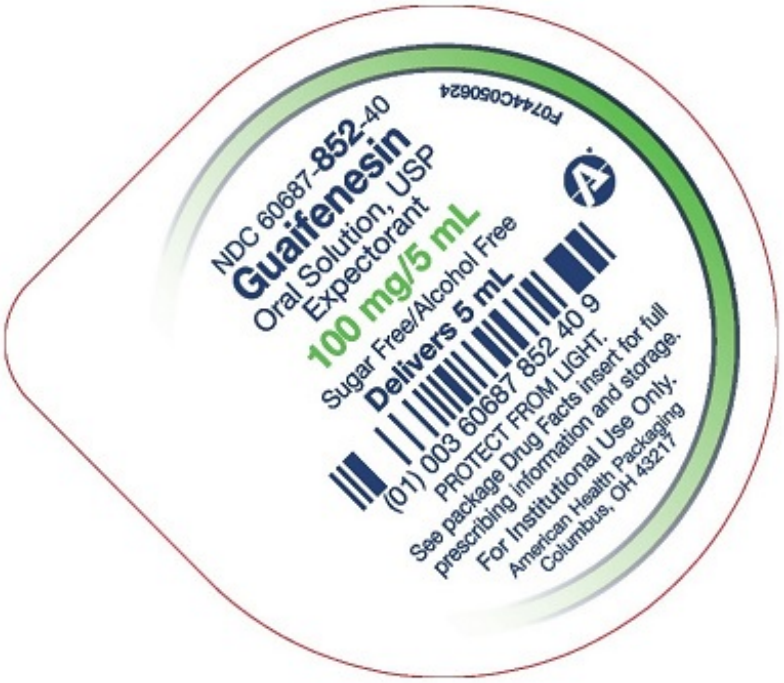
Usual Dosage: See attached Drug Facts.

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

FOR INSTITUTIONAL USE ONLY

T0744C050624 R0624

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



NDC 60687- **852**-40

Guaifenesin
Oral Solution, USP
Expectorant

100 mg per 5 ml

Sugar Free/Alcohol Free
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

F0744C050624

Package/Label Principal Display Panel – 200 mg per 10 mL – Label

Case NDC 60687- **863**-56/Cup NDC 60687- **863**-42

Guaifenesin
Oral Solution USP
Expectorant

200 mg per 10 ml

Sodium Content: 8 mg/10 ml
SUGAR FREE / ALCOHOL FREE
Raspberry 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

T0744C100624 R0624

Package/Label Principal Display Panel – 200 mg per 10 mL – Cup Lid

NDC 60687- **863**-42

Guaifenesin
Oral Solution, USP
Expectorant

200 mg per 10 ml

Sodium Content: 8 mg/10 ml
Sugar Free/Alcohol Free
Delivers 10 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

F0744C100624

Package/Label Principal Display Panel – 300 mg per 15 mL – Label

Case NDC 60687- **874**-16/Cup NDC 60687- **874**-44

Guaifenesin
Oral Solution USP
Expectorant

300 mg per 15 ml

Sodium Content: 12 mg/15 ml
SUGAR FREE / ALCOHOL FREE
Raspberry Flavor

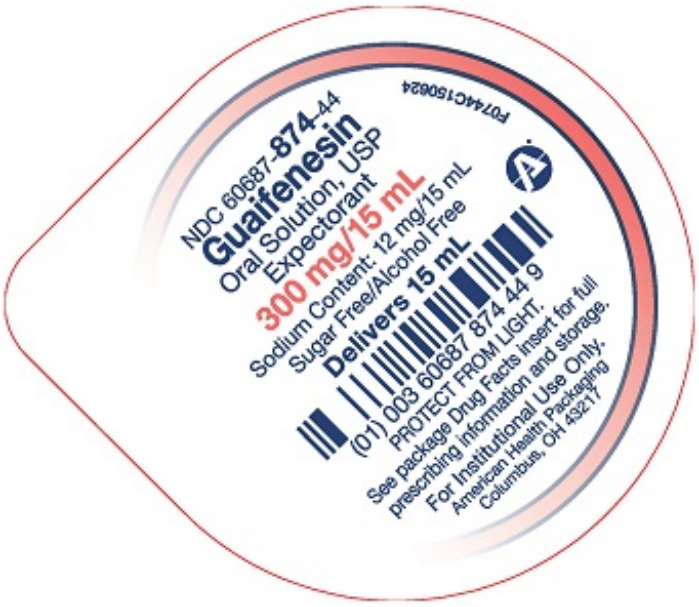
Usual Dosage: See attached Drug Facts.

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

FOR INSTITUTIONAL USE ONLY

T0744C150624 R0624

Package/Label Principal Display Panel – 300 mg per 15 mL – Cup Lid



NDC 60687- **874**-44

Guaifenesin
Oral Solution, USP
Expectorant

300 mg per 15 ml

Sodium Content: 12 mg/15 ml
Sugar Free/Alcohol Free
Delivers 15 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

F0744C150624

GUAIFENESIN

guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60687-852
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics			
Color	red	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-852-17	10 in 1 CASE	10/20/2024	
1	NDC:60687-852-46	10 in 1 TRAY		
1	NDC:60687-852-40	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	10/20/2024	

GUAIFENESIN

guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60687-863
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	red	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60687-863-56	10 in 1 CASE	10/20/2024	
1	NDC:60687-863-48	10 in 1 TRAY		
1	NDC:60687-863-42	10 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	10/20/2024	

GUAIFENESIN

guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60687-874
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	300 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-874-16	10 in 1 CASE	10/20/2024	
1	NDC:60687-874-50	10 in 1 TRAY		
1	NDC:60687-874-44	15 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	10/20/2024	

Labeler - American Health Packaging (929561009)

Revised: 10/2024 American Health Packaging