

GUAIFENESIN- guaifenesin solution
Pharmaceutical Associates, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

GUAIFENESIN

Expectorant
SUGAR FREE / ALCOHOL FREE

DESCRIPTION

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

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.

Sodium Content: 4 mg/5 mL

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.

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 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 to under 6 years of age	2.5 to 5 mL (½ to 1 teaspoonful) every 4 hours
children under 2 years of age	consult a physician

Guaifenesin Oral Solution USP is a red, raspberry flavored solution supplied in the following oral dosage forms:

NDC 0121-0744-04: 4 fl oz (120 mL) bottle

NDC 0121-0744-08: 8 fl oz (237 mL) bottle

NDC 0121-0744-16: 16 fl oz (473 mL) bottle

NDC 0121-1744-05: 5 mL unit dose cup

NDC 0121-1744-00: Case contains 100 unit dose cups of 5 mL (0121-1744-05) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-1488-10: 10 mL unit dose cup

NDC 0121-1488-00: Case contains 100 unit dose cups of 10 mL (0121-1488-10) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-2232-15: 15 mL unit dose cup

NDC 0121-2232-00: Case contains 100 unit dose cups of 15 mL (0121-2232-15) packaged in 10 trays of 10 unit dose cups each.

STORAGE

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

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0744-16

Quality®

Value

Guaifenesin Oral Solution USP

100 mg/5 mL

EXPECTORANT

Compare to the
active ingredient in

*Robitussin®

**SUGAR FREE/ALCOHOL FREE
LOOSENS AND RELIEVES
CHEST CONGESTION**

16 fl oz (473 mL)

**Pharmaceutical
Associates, Inc.**
Greenville, SC 29605

Drug Facts

Active ingredient (in each 5 mL teaspoonful) Purpose
Guaifenesin 100 mg..... 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.
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.

*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.

LOT:
EXP.

NDC 0121-0744-16

Quality Value®

**Guaifenesin
Oral Solution USP**

100 mg/5 mL

EXPECTORANT

Compare to the
active ingredient in
*Robitussin®

**SUGAR FREE/ALCOHOL FREE
LOOSENS AND RELIEVES
CHEST CONGESTION**

16 fl oz (473 mL)

pai Pharmaceutical Associates, Inc.
Greenville, SC 29605

Drug Facts (continued)

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

age	dose
adults and children 12 years and over	2-4 teaspoonfuls every 4 hours
children 6 years to under 12 years	1-2 teaspoonfuls every 4 hours
children 2 years to under 6 years	1/2-1 teaspoonful every 4 hours
under 2 years	ask a doctor

Other information
■ store at 20° -25° C (68° -77° F)
■ packaged with tamper evident seal around cap
■ sodium content 4 mg/5 mL

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.

R04/05



N 3 0121-0744-16 7

PRINCIPAL DISPLAY PANEL - 5 mL Cup Label

Delivers 5 mL

NDC 0121-1744-05

G UAIFENESIN O RAL S OLUTION USP

100 mg/5 mL

Sugar Free/Alcohol Free

EXPECTORANT

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT



PRINCIPAL DISPLAY PANEL - 10 mL Cup Label

Delivers 10 mL

NDC 0121-1488-10

G UAIFENESIN O RAL S OLUTION USP

200 mg/10 mL

Sugar Free/Alcohol Free

EXPECTORANT

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT



PRINCIPAL DISPLAY PANEL - 15 mL Cup Label

Delivers 15 mL

NDC 0121-2232-15

G UAIFENESIN O RAL S OLUTION USP

300 mg/15 mL

Sugar Free/Alcohol Free

EXPECTORANT

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT



GUAIFENESIN

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-0744
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 (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	

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:0121-0744-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2002	
2	NDC:0121-0744-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2002	
3	NDC:0121-0744-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/01/2002	

GUAIFENESIN

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-1744
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 (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
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:0121-1744-00	10 in 1 CASE	09/01/2002	
1		10 in 1 TRAY		
1	NDC:0121-1744-05	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 final	part341	09/01/2002	

GUAIFENESIN

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-1488
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 (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
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:0121-1488-00	10 in 1 CASE	09/01/2002	
1		10 in 1 TRAY		
1	NDC:0121-1488-10	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 final	part341	09/01/2002	

GUAIFENESIN

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-2232
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 (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
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:0121-2232-00	10 in 1 CASE	09/01/2002	
1		10 in 1 TRAY		
1	NDC:0121-2232-15	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 final	part341	09/01/2002	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0744, 0121-1744, 0121-1488, 0121-2232)

Revised: 9/2021

Pharmaceutical Associates, Inc.