GUAIFENESIN- guaifenesin solution
PAI Holdings, LLC

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

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, 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: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 Drug	M012	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, 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: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 Drug	M012	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, 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: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 Drug	M012	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, 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: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 Drug	M012	09/01/2002	

Labeler - PAI Holdings, LLC (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	manufacture(0121-0744, 0121-1744, 0121-1488, 0121-2232)

Revised: 6/2022 PAI Holdings, LLC