GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate 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 and Codeine Phosphate

Drug Facts

Active ingredients in each 5 mL (teaspoonful)	***Purposes***
Codeine Phosphate, USP 10 mg	Cough Suppressant
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritations as may occur with the common cold or inhaled irritants
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive

Warnings

Do not use

- in adults and children who have a chronic pulmonary disease or shortness of breath, or children who are taking other drugs, unless directed by a doctor.

Ask a doctor before use if you have

- a cough with too much phlegm (mucus)
- a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives, tranquilizers and drugs used for depression, especially monoamine oxidase inhibitors (MAOIs). These combinations may cause greater sedation (drowsiness) than is caused by the product used alone.

Stop use and ask a doctor if

- cough lasts for more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These can be signs of a serious condition.
- may cause or aggravate constipation

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

- Use of codeine-containing preparation is not recommended for children under 2 years of age.

Directions

- take every 4 hours
- do not exceed 6 doses in 24 hours
- a special measuring device should be used to give an accurate dose of this product to children under 6 years of age
- giving a higher dose than recommended by a doctor can result in serious side effects for a child

adults and children 12 years and over	10 mL (2 teaspoonfuls)
children 6 to under 12 years of age	5 mL (1 teaspoonful)
children under 6 years of age	Consult a doctor

Other information

- *Sodium Content:* 5 mg/5 mL
- Tamper evident: Do not use if seal under cap is broken or missing
- Keep container closed and store away from heat
- Store at 20°- 25°C (68°-77°F)

Inactive ingredients

Citric acid, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 6, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin and sorbitol.

Questions or comments?

Call 1-800-845-8210 or visit paipharma.com

Serious side effects associated with use of this product may be reported to this number.

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0775-16

Guaifenesin and Codeine
Phosphate Oral Solution USP
CV

100 mg/10 mg per 5 mL

Expectorant / Cough Suppressant

Alcohol Free / Sugar Free

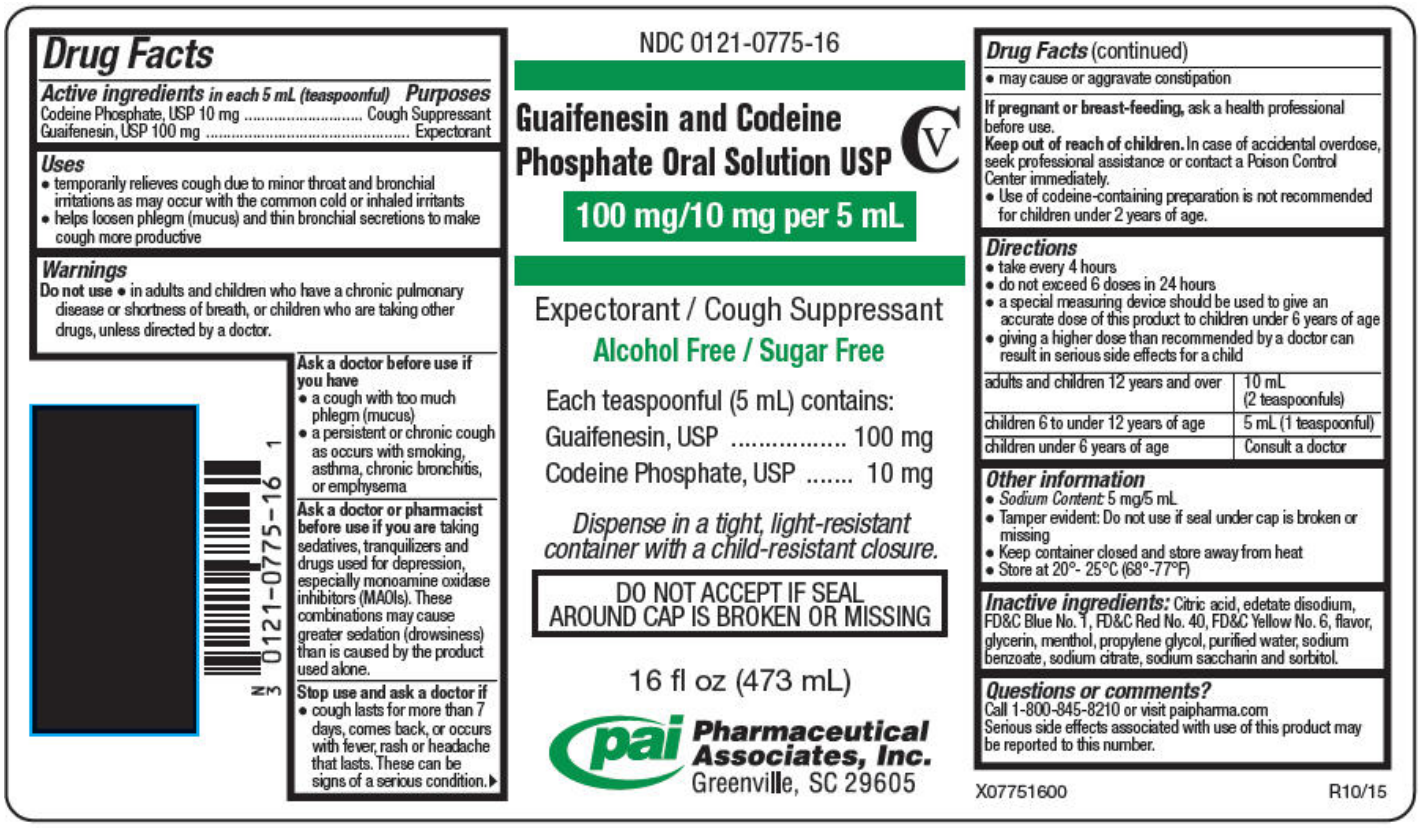
Each teaspoonful (5 mL) contains:
Guaifenesin, USP 100 mg
Codeine Phosphate, USP 10 mg

Dispense in a tight, light-resistant
container with a child-resistant closure.

DO NOT ACCEPT IF SEAL
AROUND CAP IS BROKEN OR MISSING

16 fl oz (473 mL)

pai
Pharmaceutical
Associates, Inc.
Greenville, SC 29605



PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label

Delivers **10 mL**

NDC 0121-1550-10

G UAIFENESIN AND

C ODEINE P HOSPHATE

O RAL S OLUTION USP

CV

200 mg/20 mg per 10 mL

Expectorant / Cough Suppressant

Alcohol Free / Sugar Free

FOR INSTITUTIONAL USE ONLY

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

SEE INSERT

A17751001

PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label - 1775

Delivers 10 mL

NDC 0121-1775-10

G UAIFENESIN AND
C ODEINE P HOSPHATE
O RAL S OLUTION USP
CV

200 mg/20 mg per 10 mL

Expectorant / Cough Suppressant
Alcohol Free / Sugar Free

FOR INSTITUTIONAL USE ONLY

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605
SEE INSERT

A17751000

GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-0775
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

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:0121-0775-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2006	
2	NDC:0121-0775-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2006	
3	NDC:0121-0775-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2006	

GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1775
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

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:0121-1775-00	10 in 1 CASE	10/01/2006	
1		10 in 1 TRAY		
1	NDC:0121-1775-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-1775-10	10 in 1 CASE	10/01/2006	
2		10 in 1 TRAY		
2		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	10/01/2006	

GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0121-1550
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
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EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

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:0121-1550-00	10 in 1 CASE	10/01/2006	
1		10 in 1 TRAY		
1	NDC:0121-1550-10	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	10/01/2006	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0775, 0121-1775, 0121-1550)

Revised: 12/2017 Pharmaceutical Associates, Inc.