

GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate solution
Cardinal Health 107, LLC

Guaifenesin and Codeine Phosphate

Drug Facts

<i>Active ingredients in each 5 mL (teaspoonful)</i>	<i>Purposes</i>
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.

X07751600 R10/15

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only.

Distributed By:

Cardinal Health

Dublin, OH 43017

LC8458470424

Principal Display Panel

GUAIFENESIN AND CODEINE

PHOSPHATE ORAL SOLUTION USP

100 mg/10 mg per 5 mL

5 CUPS



CV

NDC 55154-5791-5

**GUAIFENESIN AND CODEINE
PHOSPHATE ORAL SOLUTION USP
100 mg/10 mg per 5 mL**

5 CUPS

Expectorant / Cough Suppressant

Alcohol Free / Sugar Free

Delivers 5 mL

See product insert for prescribing information, precautions
and warnings.

STORAGE: Store at 20° to 25° C (68° to 77° F)

[See USP Controlled Room Temperature]

WARNING: This Unit Dose package is not child resistant
and is Intended for Institutional Use Only.

Keep this and all drugs out of the reach of children.

PHARMACEUTICAL ASSOCIATES, INC.

201 Delaware Street
GREENVILLE, SC 29605

(800) 845-8210

www.paipharma.com

Distributed by Cardinal Health

Dublin, OH 43017

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GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-5791(NDC:0121- 1775)
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		100 mg/10 mg per 5 mL

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
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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:55154-5791-5	5 in 1 BAG	06/27/2023	
1		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	06/27/2023	

Labeler - Cardinal Health 107, LLC (118546603)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	REPACK(55154-5791)

