

GUAIATUSSIN AC SUGAR FREE- guaifenesin and codeine phosphate liquid
Cardinal Health 107, LLC

Drug Facts

Active ingredients (in each 5 mL teaspoonful)

Codeine Phosphate, USP 10 mg

Guaifenesin, USP 100 mg

Purposes

Cough Suppressant

Expectorant

Keep Out of Reach of Children

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 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 preparations 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	2 teaspoonfuls
children 6 to under 12 years of age	1 teaspoonfuls
children under 6 years of age	Consult a doctor

Other information

- **each (5 mL) teaspoon contains:** 1 mg sodium
- **Tamper evident:** Do not use if seal under cap is broken or missing.
- Keep container closed and away from heat.
- Store at room temperature 15°- 30°C (59°-86°F)

Inactive Ingredients

alcohol 3.5% v/v, artificial cherry flavor, caramel, citric acid, FD&C red # 40, glycerin, polyethylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol solution.

Questions or comments?

Call **1-800-932-5676**, Mon.-Thurs 9:00 am thru 4:30 pm EST, Fri. 9:00 am thru 2:30 pm EST.

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

Distributed By:
Cardinal Health
Dublin, OH 43017
LC2838411118

Package/Label Principal Display Panel

Guaiatussin AC CV
5 Cups
Delivers 5 mL



NDC 55154-9627-5



GUAIIATUSSIN AC

5 CUPS

Delivers 5 mL

Sugar-Free

Expectorant /Cough Suppressant

Each teaspoonful (5 mL) contains: Guaifenesin 100 mg,
Codeine Phosphate 10 mg, and Alcohol 3.5 % v/v.

Each (5 mL) teaspoon contains: 1 mg sodium.

Usual Dosage: See product insert for prescribing information,
precautions and warnings.

STORAGE: Store at room temperature 15° - 30° C
(59° - 86° F).

STORE AWAY FROM HEAT

RX ONLY

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.

Trust, Confidence, Commitment.

Hi-Tech Pharmacal Co., Inc
Amityville, NY 11701
1-800-262-9010
www.hitechpharm.com.

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Dublin, OH 43017
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GUAIATUSSIN AC SUGAR FREE

guaifenesin and codeine phosphate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-9627(NDC:50383-087)
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CARAMEL (UNII: T9D99G2B1R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (artificial cherry flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-9627-5	5 in 1 BAG	09/08/2010	
1		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	09/08/2010	

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 11/2023

Cardinal Health 107, LLC