

**GUAIATUSSIN AC SUGAR FREE- guaifenesin and codeine phosphate liquid**  
**Akorn Operating Company LLC**

*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.*

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**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.

### Package/Label Principal Display Panel

**AKORN**  
NDC 50383-087-16  
**Guaiatussin AC**  
**Sugar-Free**

- Expectorant
- Cough Suppressant

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

Distributed by:  
Akorn Operating Company LLC  
Gurnee, IL 60031  
16 fl oz (473 mL)

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

**Use** - 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

**Drug Facts (continued)**  
**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

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Unwashed

**AKORN**

**NDC 50383-087-16**

**Guaiatussin AC**

**Sugar-Free**

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- **Cough Suppressant**

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**Distributed by:**

**Akorn Operating Company LLC**

**Gurnee, IL 60031**

**16 fl oz (473 mL)**

# GUAIATUSSIN AC SUGAR FREE

guaifenesin and codeine phosphate liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50383-087
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CV

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (artificial cherry flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-087-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2010	
2	NDC:50383-087-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2010	
3	NDC:50383-087-07	10 in 1 CASE	09/08/2010	
3		10 in 1 TRAY		
7	NDC:50383-	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a		

087-05	Combination Product		
4 NDC:50383-087-12	10 in 1 CASE	09/08/2010	
4	10 in 1 TRAY		
4 NDC:50383-087-10	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	09/08/2010	

**Labeler** - Akorn Operating Company LLC (117696873)

**Registrant** - Akorn Operating Company LLC (117693100)

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn Operating Company LLC		117696873	MANUFACTURE(50383-087) , PACK(50383-087)

Revised: 10/2022

Akorn Operating Company LLC