

**CODEINE PHOSPHATE AND GUAIFENESIN- codeine phosphate and guaifenesin liquid  
ATLANTIC BIOLOGICALS CORP.**

*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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**Codeine Phosphate and Guaifenesin**

**CV**

***Active ingredients (in each teaspoonful (5 mL))***

Codeine phosphate USP 10 mg

Guaifenesin USP 100 mg

***Purpose***

Antitussive (Cough Suppressant)

Expectorant

***Uses***

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- relieves your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves cough associated with the common cold

***Warnings***

**Ask your Doctor if:**

- you have a persistent or chronic cough, this may be a sign of a serious condition
- you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

**When using this product**

- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age
- may cause or aggravate constipation

**Stop use and ask a doctor if**

- symptoms do not improve within 7 days, tend to recur or are accompanied by fever, rash, or persistent headache. These may be symptoms of a serious condition.

**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.

**Directions**

- **do not exceed 6 doses in 24 hours**

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

**Other information**

Store at controlled room temperature 20° to 25°C (68° to 77°F)

**Inactive ingredients**

Cherry flavor, citric acid, ededate disodium, FD&C red #40, glycerin, maltodextrin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol, sucralose

**DISTRIBUTED BY:**

**ATLANTIC BIOLOGICALS CORP.**

**20101 N.E 16TH PLACE**

**MIAMI, FL 33179**

**PRINCIPAL DISPLAY PANEL**

NDC 17856-0208-1

CODEINE PHOSPHATE-GUAIFENESIN

ORAL SOL 10-100mg/mL CUP 72

**NDC 17856-0208-01**

**Codeine Phosphate-Guaifenesin**

**ORAL SOLUTION**

**10-100 mg/ 5 mL**



ANTITUSSIVE (COUGH SUPPRESSANT/EXPECTORANT)

**DELIVERS 5 mL CUP**

Each 5 mL (1 teaspoonful) contains:

Codeine phosphate USP ..... 10 mg

Guaifenesin USP ..... 100 mg

**PACKAGING INFORMATION:**

Dosage per Cup: 5 mL

Cup(s) per Case: 72

See package insert for complete prescribing information.

Other information:

Store at controlled room temperature 20° - 25°C (68°-77°F)

KEEP CODEINE PHOSPHATE-GUAIFENESIN  
AND ALL MEDICINES OUT OF THE REACH OF CHILDREN

Marketed by: BioRamp  
Fort Lauderdale, FL 33309  
Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560  
Distributed by: Atlantic Biologicals Corp.  
20101 N.E. 16th Place  
Miami, FL 33179

\*Retain box label and package insert for drug information.

**Questions or Comments:**

**Call 1-800-509-7592**

Lot No: XXXXXX  
MFG Lot No: XXXXXX  
Exp Date: XX/XX/XXXX



17856020801

**CODEINE PHOSPHATE AND GUAIFENESIN**

codeine phosphate and guaifenesin liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0208(NDC:54932-208)
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CV

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

## 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:17856-0208-1	72 in 1 BOX, UNIT-DOSE	09/24/2018	
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 FINAL	part341	09/24/2018	

**Labeler** - ATLANTIC BIOLOGICALS CORP. (047437707)

## Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0208) , relabel(17856-0208)

Revised: 9/2018

ATLANTIC BIOLOGICALS CORP.