

CODEINE-GUAIFENESIN- codeine phosphate and guaifenesin solution
ATLANTIC BIOLOGICALS CORP.

Codeine-Guaifenesin

Drug Facts

<i>Active ingredients (in each 5 mL = 1 tsp)</i>	<i>Purpose</i>
Codeine phosphate, USP 10 mg	Antitussive
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
 - 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.

Warnings

Ask your doctor before use if

- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent 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 and 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 the 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 15°-30°C (59°-86°F).

You may report side effects by calling 1-844-221-7294 or FDA at 1-800-FDA-1088.

Inactive ingredients

Cherry Flavor, Citric Acid Anhydrous, Glycerin, Masking Agent, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sorbitol Solution, Sucralose.

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 17856-0273-01

CODEINE-GUAIFENESIN 10-100MG - 5 ML CUP 72 ct UD

Antitussive/Expectorant

Sugar Free, Alcohol Free, Dye Free

Each 5 mL (1 teaspoonful) contains:

Codeine phosphate, USP

10 mg

Guaifenesin, USP

100 mg

(WARNING: May be habit-forming)

17856-0273-01
CODEINE-GUAIFENESIN
ORAL SOLUTION
10MG/100MG/5ML
DELIVERS 5 ML



See package insert for indications and dosage schedule

Antitussive / Expectorant Sugar, Alcohol, Dye Free
Store at Controlled Room Temperature 15°-30°C (59°-86°F).
**** Keep this and all Medication out of the reach of children****



17856-0273-01

Dosage 10MG/100MG/5ML

CODEINE-GUAIFENESIN

Qty: 72 CUPS

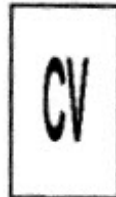


GTIN: 00117856027317

S/N: 01554601

Exp: 04/12/22

Lot: 015546



Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
Miami FL 33179

Rev.08/21

Call to Reorder: 800.509.7592

CODEINE-GUAIFENESIN

codeine phosphate and guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0273(NDC:69367-272)
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Codeine Phosphate (UNII: C6105Y1MNG) (Codeine Anhydrous		

Codeine Phosphate (UNII: G5L05T1MNO) (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	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0273-1	72 in 1 BOX, UNIT-DOSE	05/08/2024	
1	NDC:17856-0273-2	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	07/15/2020	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-0273)