CODEINE-GUAIFENESIN- codeine phosphate and guaifenesin solution
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.

Codeine-Guaifenesin

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	***Purpose***
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)

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: GSL05Y1MN6) (Codeine Anhydrous		

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
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	11/22/2022	
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 FINAL	part341	07/15/2020	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

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

Revised: 11/2022 ATLANTIC BIOLOGICALS CORP.