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

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	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)

Revised: 5/2024 ATLANTIC BIOLOGICALS CORP.