CODEINE PHOSPHATE AND GUAIFENESIN- codeine phosphate and guaifenes in liquid BioRamo, 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.

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

Other information

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

Inactive ingredients

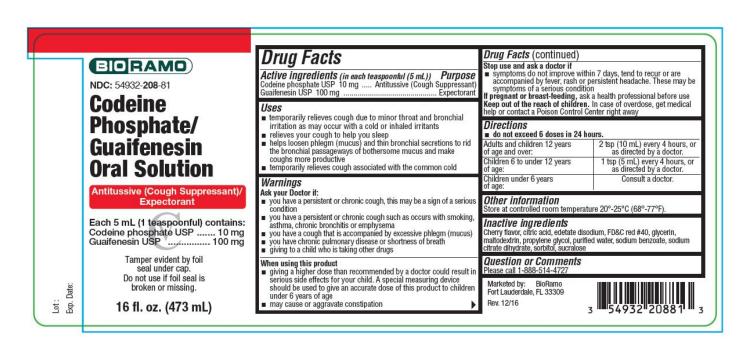
Cherry flavor, citric acid, ededate disodium, FD&C red #40, glycerin, maltodextrin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol, sucralose

Question or Comments

Please call 1-888-514-4727

Marketed by: BioRamo Fort Lauderdale, FL 33309

PRINCIPAL DISPLAY PANEL



CODEINE PHOSPHATE AND GUAIFENESIN

codeine phosphate and guaifenesin liquid

Product Information	oduct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54932-208	
Route of Administration	ORAL	DEA Schedule	CV	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	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 MO NO HYDRATE (UNII: 2968 PHW8 QP)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54932-208- 85	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/17/20 17	
2	NDC:54932-208- 86	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/17/20 17	
3	NDC:54932-208- 81	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/17/20 17	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	0 1/17/20 17		

Labeler - BioRamo, LLC (968948443)

Revised: 1/2020 BioRamo, LLC