GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate solution
NuCare Pharmaceuticals,Inc.

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.

Guaifenesin and Codeine Phosphate

Drug Facts

Active ingredients in each 5 mL (teaspoonful)	***Purposes***
Codeine Phosphate, USP 10 mg	Cough Suppressant
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritations as may occur with the common cold or inhaled irritants
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive

Warnings

Do not use

- in adults and children who have a chronic pulmonary disease or shortness of breath, or children who are taking other drugs, unless directed by a doctor.

Ask a doctor before use if you have

- a cough with too much phlegm (mucus)
- a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives, tranquilizers and drugs used for depression, especially monoamine oxidase inhibitors (MAOIs). These combinations may cause greater sedation (drowsiness) than is caused by the product used alone.

Stop use and ask a doctor if

- cough lasts for more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These can be signs of a serious condition.
- may cause or aggravate constipation

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

- Use of codeine-containing preparation is not recommended for children under 2 years of age.

Directions

- take every 4 hours
- do not exceed 6 doses in 24 hours
- a special measuring device should be used to give an accurate dose of this product to children under 6 years of age
- giving a higher dose than recommended by a doctor can result in serious side effects for a child

adults and children 12 years and over	10 mL (2 teaspoonfuls)
children 6 to under 12 years of age	5 mL (1 teaspoonful)
children under 6 years of age	Consult a doctor

Other information

- *Sodium Content:* 5 mg/5 mL
- Tamper evident: Do not use if seal under cap is broken or missing
- Keep container closed and store away from heat
- Store at 20°- 25°C (68°-77°F)

Inactive ingredients

Citric acid, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 6, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin and sorbitol.

Questions or comments?

Call 1-800-845-8210 or visit paipharma.com

Serious side effects associated with use of this product may be reported to this number.

PRINCIPAL DISPLAY PANEL -

GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-1350(NDC:0121-0775)
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

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:68071-1350-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2006	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-1350)