

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

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**Codeine-Guaifenesin Oral Solution**

***Active ingredient***

***(in each teaspoonful (5 mL))***

Codeine Phosphate USP 10 mg

***Purpose***

Antitussive

***Active ingredient***

***(in each teaspoonful (5 mL))***

Guaifenesin USP 100 mg

***Purpose***

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 makes cough 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 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).

**Inactive ingredients**

Cherry Flavor, Citric Acid, Glycerin, Propylene glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

**Principal Display Panel**

# NuCare Pharmaceuticals, Inc.

NDC: 68071-5173-4  
Cod.Phos.10mg/Guaifenesin 100mg/5mL

Cod.Phos.10mg/Guaifenesin 100mg/5mL  
Lot: 000000 NDC: 68071-5173-04  
MFR NDC: 58657-500 04 Exp.: 00-00  
Serial# 00000000002

Cod.Phos.10mg/Guaifenesin 100mg/5mL  
Lot: 000000 NDC: 68071-5173-04  
MFR NDC: 58657-500 04 Exp.: 00-00  
Serial# 00000000002

4oz Oral Soln.



See manufacturer's label  
for full list of ingredients.

Product #: R0274004  
Rx Only



GTIN 00368071517347  
Serial# 00000000002  
Exp. Date 00-00  
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: 3 6807151734  
Method Pharmaceuticals, LLC  
Arlington, TX 76006  
Packaged By:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92667

Take \_\_\_\_\_teaspoonful(s) every \_\_\_\_\_  
hours \_\_\_\_\_times a day.

Rev 01/01/19  
WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

## CODEINE-GUAIFENESIN

codeine phosphate and guaifenesin solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-5173(NDC:58657-500)
Route of Administration	ORAL	DEA Schedule	CV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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 CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

### Product Characteristics

Color		Score	
Shape		Size	

<b>Flavor</b>	CHERRY	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-5173-4	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	04/01/2014		

**Labeler** - NuCare Pharmaceuticals, Inc. (010632300)

### Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-5173)

Revised: 6/2024

NuCare Pharmaceuticals, Inc.