

## **CODEINE-GUAIFENESIN- codeine phosphate and guaifenesin solution**

### **Proficient Rx LP**

*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.*

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## **Codeine-Guaifenesin**

### **Drug Facts**

<b>Active ingredients (in each 5 mL = 1 tsp)</b>	<b>Purpose</b>
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.

### PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 71205-624-04

Codeine-Guaifenesin

Oral Solution

10-100 mg/5 mL

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)

4 fl. oz. (118 mL)

Scan Here 

 NDC 71205-624-04

**C-V**

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

**Codeine-Guaifenesin**  
4 fl. oz. (118 mL) Oral Solution  
Lot #:00000 SN# MASTER  
NDC 71205-624-04 Exp:00/00/00

Codeine-Guaifenesin  
4 fl. oz. (118 mL) Oral Solution  
Lot #:00000 SN# MASTER  
NDC 71205-624-04 Exp:00/00/00

Codeine-Guaifenesin  
4 fl. oz. (118 mL) Oral Solution  
Lot #:00000 SN#MASTER  
NDC 71205-624-04 Exp:00/00/00

**Codeine-Guaifenesin**  
4 fl. oz. (118 mL) Oral Solution  
Lot #:00000 SN# MASTER  
Exp: 00/00/00  
Lot #:00000

GTIN: 00371205624040  
SN# MASTER  
Exp. 00/00/00  
Lot #:00000

**Codeine-Guaifenesin**  
4 fl. oz. (118 mL) Oral Solution  
Each 5ml (1tsp) contains: Codeine Phosphate, USP  
10mg Antitussive/ Guaifenesin, USP 100mg  
Expectorant

See package insert. **(WARNING: May be habit-forming)**

Product ID: SG062404

Mfr. For: Westminster Pharmaceuticals, LLC Nashville, TN 37217

Store at controlled room temperature 15°-30°C (59°- 86°F).

Keep medication out of the reach of children

## CODEINE-GUAIFENESIN

codeine phosphate and guaifenesin solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71205-624(NDC:69367- 272)
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Codeine Phosphate</b> (UNII: GSL05Y1MN6) (Codeine Anhydrous - UNII:UX6OWY2V7J)	Codeine Phosphate	10 mg in 5 mL
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-624-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/15/2020	

**Labeler** - Proficient Rx LP (079196022)

## Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-624)

Revised: 12/2021

Proficient Rx LP