GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate 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.

Guaifensin and Codeine Phosphate
Oral Solution USP
CV

DESCRIPTION

Each 5 mL (1 teaspoonful) contains Guaifenesin, USP 100 mg and Codeine Phosphate, USP 10 mg.

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.

Sodium Content: 5 mg/5 mL

Under federal law, Guaifenesin and Codeine Phosphate Oral Solution USP is available without a prescription. Certain state laws may differ.

Click here to enter text.

[Enter Active Ingredient here]

[Enter Inactive Ingredients here]

ACTIONS

This product combines the expectorant, guaifenesin, with the cough suppressant, codeine. Guaifenesin enhances the output of lower respiratory tract fluid. The enhanced flow of less viscid secretions promotes and facilitates the removal of mucus. Codeine is a centrally acting agent which elevates the threshold for cough.

As a result, dry, unproductive coughs become more productive and less frequent.

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[Enter Purpose here]

INDICATIONS

Temporarily controls cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants. Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

WARNINGS

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a physician. Do not take this

product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a physician. Adults and children who have a chronic pulmonary disease or shortness of breath, or children who are taking other drugs, should not take this product unless directed by a physician. May cause or aggravate constipation. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Professional Note: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Click here to enter text.

[Enter Keep Out of Reach of Children here]

DRUG INTERACTION PRECAUTION

Caution should be used when taking this product with sedatives, tranquilizers and drugs used for depression, especially monoamine oxidase inhibitors (MAOIs). These combinations may cause greater sedation (drowsiness) than is caused by the products used alone. (See **WARNINGS**)

DOSAGE and ADMINISTRATION

Take orally as stated below or use as directed by a physician. *Adults and children 12 years of age and over:* 10 mL (2 teaspoonfuls) every 4 hours, not to exceed 12 teaspoonfuls in a 24-hour period; *Children 6 to under 12 years:* 5 mL (1 teaspoonful) every 4 hours, not to exceed 6 teaspoonfuls in a 24-hour period; *Children under 6 years:* consult a physician. 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 physician could result in serious side effects for a child. Use of codeine-containing preparations is not recommended for children under 2 years of age. Do not exceed recommended dosage.

STORAGE

Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F). [See USP] Protect from light.

HOW SUPPLIED

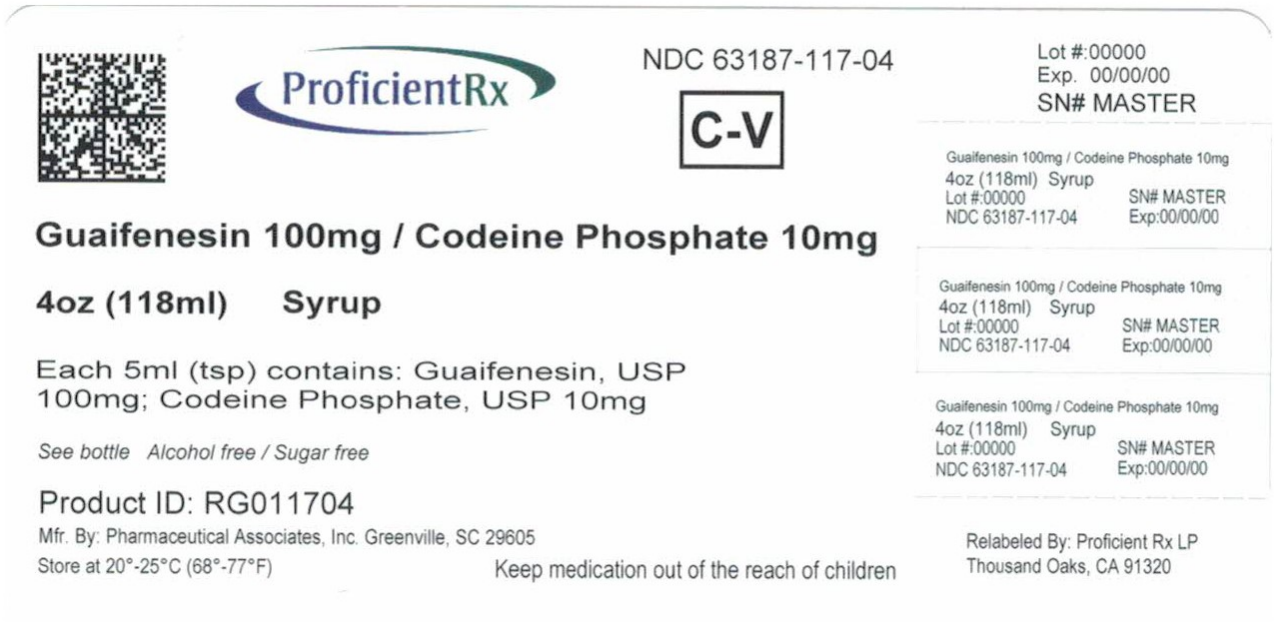
Guaifenesin and Codeine Phosphate Oral Solution USP (red color-cherry flavor) is supplied in the following oral dosage forms: NDC 63187-117-12 (4 fl oz bottle).

Pharmaceutical
Associates, Inc.
Greenville, SC 29605

R08/06

Repackaged by:
Proficient Rx LP
Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL



GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-117(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 ACETATE (UNII: DSO12WL7AU)	

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:63187-117-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2014	

Marketing Information

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

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(63187-117) , REPACK(63187-117)

Revised: 12/2019 Proficient Rx LP