GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate solution
Dispensing Solutions, 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.

Guaifensin and Codeine Phosphate
Oral Solution USP
CV

ACTIVE INGREDIENT

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

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

INACTIVE INGREDIENT

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

PURPOSE

Expectorant / Cough Suppressant

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.

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.

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).

KEEP OUT OF REACH OF CHILDREN

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.

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 682588-8904-04 (4 fl oz bottle)

Pharmaceutical
Associates, Inc.
Greenville, SC 29605

R08/06

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 68258-8904-04

Guaifenesin and Codeine
Phosphate Oral Solution USP
CV

100 mg/10 mg per 5 mL

Expectorant / Cough Suppressant

Alcohol Free / Sugar Free

Each teaspoonful (5 mL) contains:
Guaifenesin, USP 100 mg
Codeine Phosphate, USP 10 mg

Dispense in a tight, light-resistant container with a child-resistant closure.

DO NOT ACCEPT IF IMPRINTED SEAL AROUND CAP IS BROKEN OR MISSING.

4 fl oz (118 mL)

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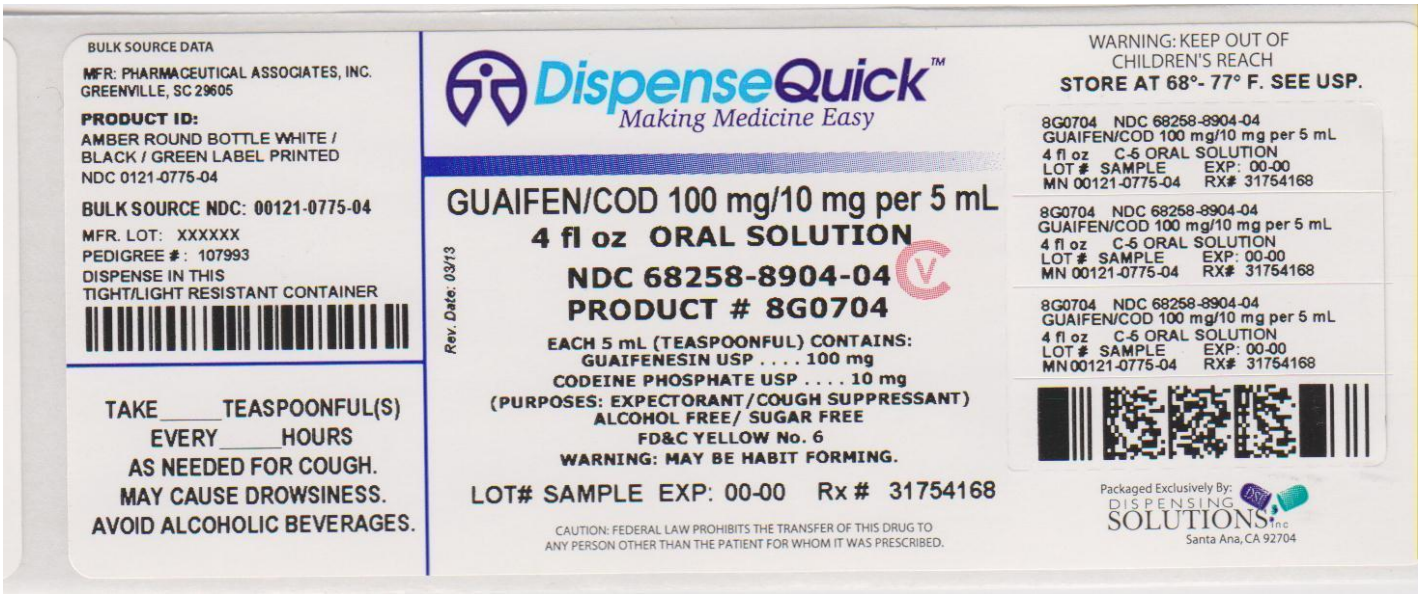
Pharmaceutical
Associates, Inc.
Greenville, SC 29605

NDC 68258-8904-04



GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68258-8904(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 (UNII: L7T10EIP3A)	
propylene glycol (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate (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:68258-8904-4	118 mL in 1 BOTTLE		

Marketing Information

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

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(68258-8904) , repack(68258-8904)

Revised: 6/2013 Dispensing Solutions, Inc.