GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate solution
Apotheca, 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 CV

ACTIVE INGREDIENT

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

ABOUT

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.

KEEP OUT OF REACH OF CHILDREN

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

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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).

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 & HOW SUPPLIED

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). 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 12634-969-04 (4 fl oz (120mL) bottle

Manufactured by:

Pharmaceutical Associates, Inc.
Greenville, SC 29605

Distrubited by:

Apotheca, Inc.

Phoenix, AZ 85006

INACTIVE INGREDIENT

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.

PRINCIPAL DISPLAY PANEL

Guaifenesin & Codeine Phosphate

Oral Solution USP

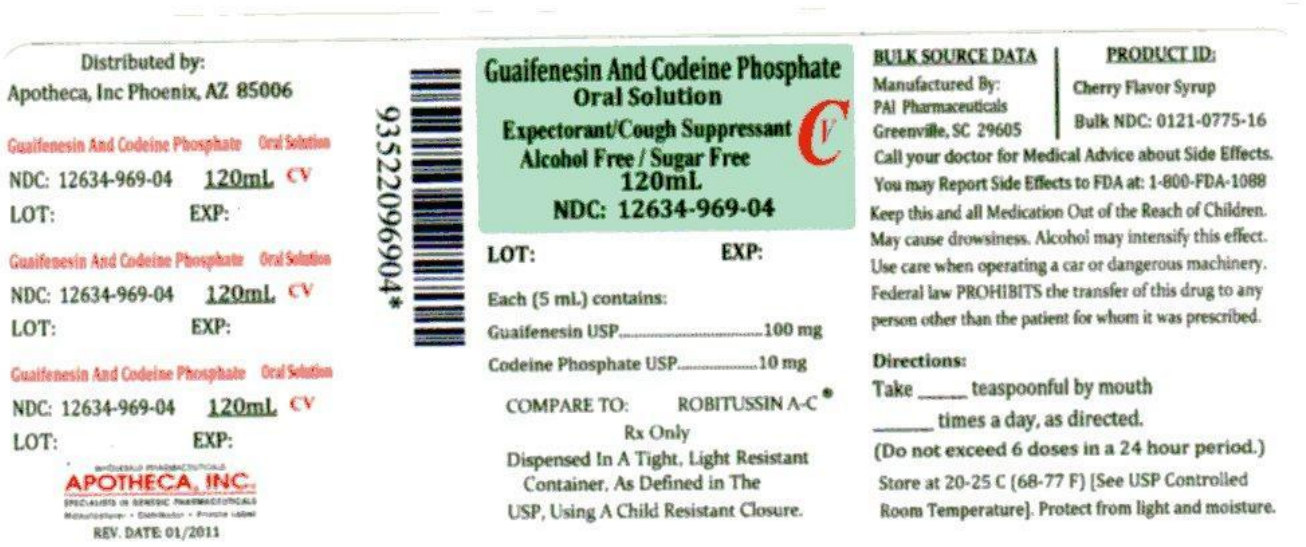
CV

Expectorant/Cough Suppressant

Alcohol Free / Sugar Free

120mL

NDC 12634-969-04



GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:12634-969(NDC:0121-1775)
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**
MENTHOL (UNII: L7T10EIP3A)	

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:12634-969-04	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/28/2011	

Labeler - Apotheca, Inc (051457844)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca, Inc		051457844	relabel(12634-969)

Revised: 10/2013 Apotheca, Inc