GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate solution
DirectRX

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

DESCRIPTION SECTION

- 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.

CONTRAINDICATIONS SECTION

Hypersensitivity to any of the ingredients

WARNINGS SECTION

- 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 INTERACTIONS SECTION

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 & ADMINISTRATION SECTION

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 AND HANDLING SECTION

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

OTC - ACTIVE INGREDIENT SECTION

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

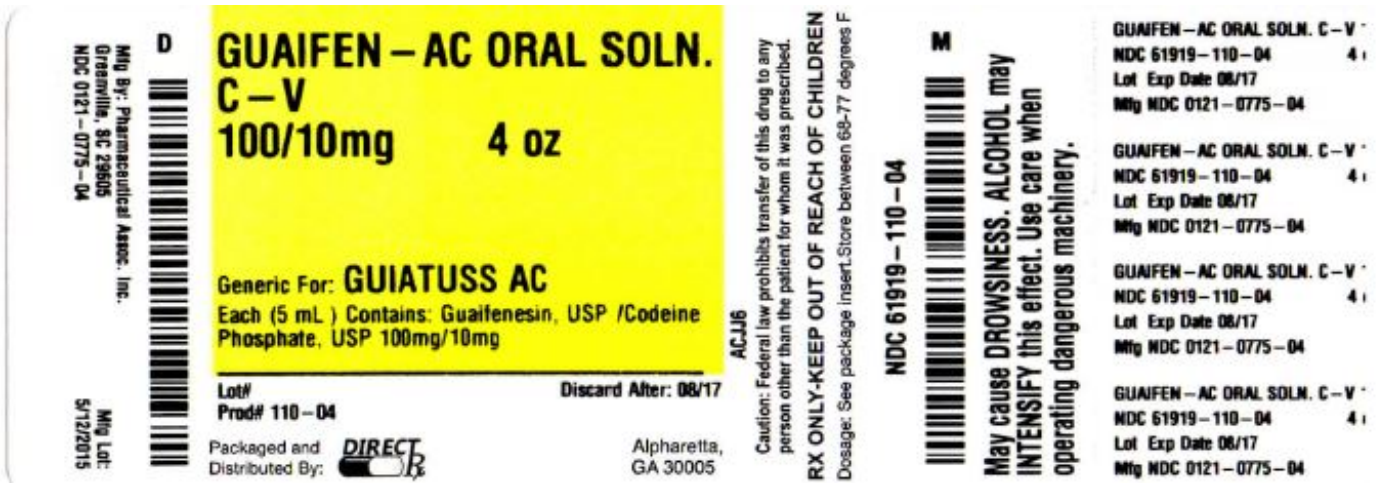
OTC - PURPOSE SECTION

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.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

KEEP OUT OF REACH OF CHILDREN

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



INDICATIONS & USAGE SECTION

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.

INACTIVE INGREDIENT SECTION

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.

GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-110(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**
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)	
menthol (UNII: L7T10EIP3A)	
propylene glycol (UNII: 6DC9Q167V3)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate (UNII: 1Q73Q2JULR)	
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:61919-110-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2015	

Labeler - DirectRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DirectRX		079254320	repack(61919-110)

Revised: 10/2015

DirectRX