GUAIFENESIN AC- guaifenesin and codeine phosphate syrup
Rising Pharmaceuticals

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Guaifenesin AC

Each teaspoon (5 mL) Contains:	
Guaifenesin USP	100 mg
Codeine Phosphate USP	10 mg

contains 3.5% alcohol v/v

INACTIVE INGREDIENTS

Alcohol 3.5%, artificial cherry flavor, caramel, citric acid, disodium edetate, FD&C Red #40, glycerin, purified water, saccharin sodium, sodium benzoate, sorbitol solution.

INDICATIONS

Temporarily relieves 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.

DIRECTIONS

Take every 4 hours or as directed by a doctor. Do not exceed 6 doses in 24 hours. **Adults and children 12 years of age and over:** Take 2 teaspoons. **Children 6 to under 12 years of age:** Give 1 teaspoon. **Children under 6 years of age:** DO NOT USE. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

WARNINGS

Do not exceed recommended dosage. Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor. 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 doctor. 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 doctor. 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. Do not use in children following a tonsillectomy and/or adenoidectomy as this could cause severe respiratory distress.

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 product used alone.

TO REPORT ADVERSE DRUG EVENTS CALL: (866) 562-4597

Dispense in a tight, light-resistant container as defined in the USP.

Store at controlled room temperature 20º - 25º C (68º - 77ºF). (see USP Controlled Room Temperature) DO NOT REFRIGERATE.

OTHER INFORMATION

Each 5 mL contains: sodium 4 mg

TAMPER-EVIDENT

Do not use this product if inner foil seal over the mouth of the bottle is cut, torn, broken or missing.

BULK CONTAINER - NOT FOR HOUSEHOLD USE.

REV 2/15

Manufactured by:
Bio-Pharm, Incorporated Levittown, PA 19057

Distributed by:
Rising Pharmaceuticals, Inc. Allendale, NJ 07401

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Rising® NDC 16571-302-16

Guaifenesin AC
Cough Syrup

CV

SUGAR-FREE

GUAIFENESIN AND CODEINE
PHOSPHATE ORAL SOLUTION, USP)
COUGH SUPPRESSANT
EXPECTORANT

Each teaspoon (5 mL) Contains: Guaifenesin USP..... 100 mg
Codeine Phosphate USP..... 10 mg

contains 3.5% alcohol v/v

*Under Federal law Guaifenesin AC is available
without a prescription. Certain State laws may differ.

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TAMPER-EVIDENT
DO NOT REFRIGERATE

ONE PINT (473 mL)

GUAIFENESIN AC

guaifenesin and codeine phosphate syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16571-302
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
Alcohol (UNII: 3K9958V90M)	
Cherry (UNII: BUC5I9595W)	
Caramel (UNII: T9D99G2B1R)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Edetate Disodium (UNII: 7FLD91C86K)	
FD&C Red no. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color	BROWN	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-302-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		03/01/2015	

Labeler - Rising Pharmaceuticals (835513529)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Pharm, Inc.		801652546	MANUFACTURE(16571-302) , ANALYSIS(16571-302) , PACK(16571-302) , LABEL(16571-302)

Revised: 12/2017 Rising Pharmaceuticals