GUAIFENESIN DAC- guaifenesin, codeine phosphate and pseudoephedrine hydrochloride liquid
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 DAC

Each teaspoon (5 mL) Contains:	
Guaifenesin USP	100 mg
Pseudoephedrine Hydrochloride USP	30 mg
Codeine Phosphate USP	10 mg

contains 1.9% alcohol v/v

INACTIVE INGREDIENTS

Alcohol 1.9%, artificial cherry flavor, caramel, citric acid, disodium edetate, FD&C Red #40, glycerin, menthol, purified water, saccharin sodium, sodium benzoate, sorbitol solution.

INDICATIONS

Temporarily relieves cough and nasal congestion as may occur with a cold. 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 4 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 if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by 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. 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. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor. If symptoms do not improve within 7 days or are accompanied by fever, consult 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.

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

DRUG INTERACTION PRECAUTION

Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains a MAOI, consult a health professional before taking this product.

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

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

OTHER INFORMATION

Each 5 mL contains: sodium 4mg

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

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Rising® NDC 16571-301-16

Guaifenesin DAC
Oral Solution
SUGAR-FREE

CV

(Guaifenesin, Pseudoephedrine
Hydrochloride and Codeine Phosphate
Oral Solution, USP)

EXPECTORANT
NASAL DECONGESTANT
COUGH SUPPRESSANT

Each teaspoon (5 mL) Contains:
Guaifenesin USP..... 100 mg
Pseudoephedrine Hydrochloride USP 30 mg
Codeine Phosphate USP 10 mg
contains 1.9% alcohol v/v

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

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

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

TAMPER-EVIDENT
DO NOT REFRIGERATE

ONE PINT (473 mL)

GUAIFENESIN DAC

guaifenesin, codeine phosphate and pseudoephedrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16571-301
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
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	30 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)	
Menthol, Unspecified Form (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:16571-301-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/01/2016	

Labeler - Rising Pharmaceuticals (835513529)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Pharm, Inc.		801652546	MANUFACTURE(16571-301) , ANALYSIS(16571-301) , PACK(16571-301) , LABEL(16571-301)

Revised: 12/2017 Rising Pharmaceuticals