GUAIFENESIN AND CODEINE PHOSPHATE- guaifenesin and codeine phosphate solution
NuCare Pharmaceuticals,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 Oral Solution, USP CV

100 mg/10 mg per 5 mL

SUGAR FREE, DYE FREE, ALCOHOL FREE

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	***Purpose***
Codeine phosphate, USP 10 mg	Cough suppressant
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
- your cough to help you sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask your doctor before use if

- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product

- giving a higher dose than recommended by a doctor could result in serious side

effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.
- may cause or aggravate constipation

Stop use and ask a doctor if
- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- Do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information

Each tsp (5 mL) contains 3 mg sodium.
Store at controlled room temperature 15°-30°C (59°-86°F). You may report side effects by calling 1-888-344-9603 or FDA at 1-800-FDA-1088.

Inactive ingredients

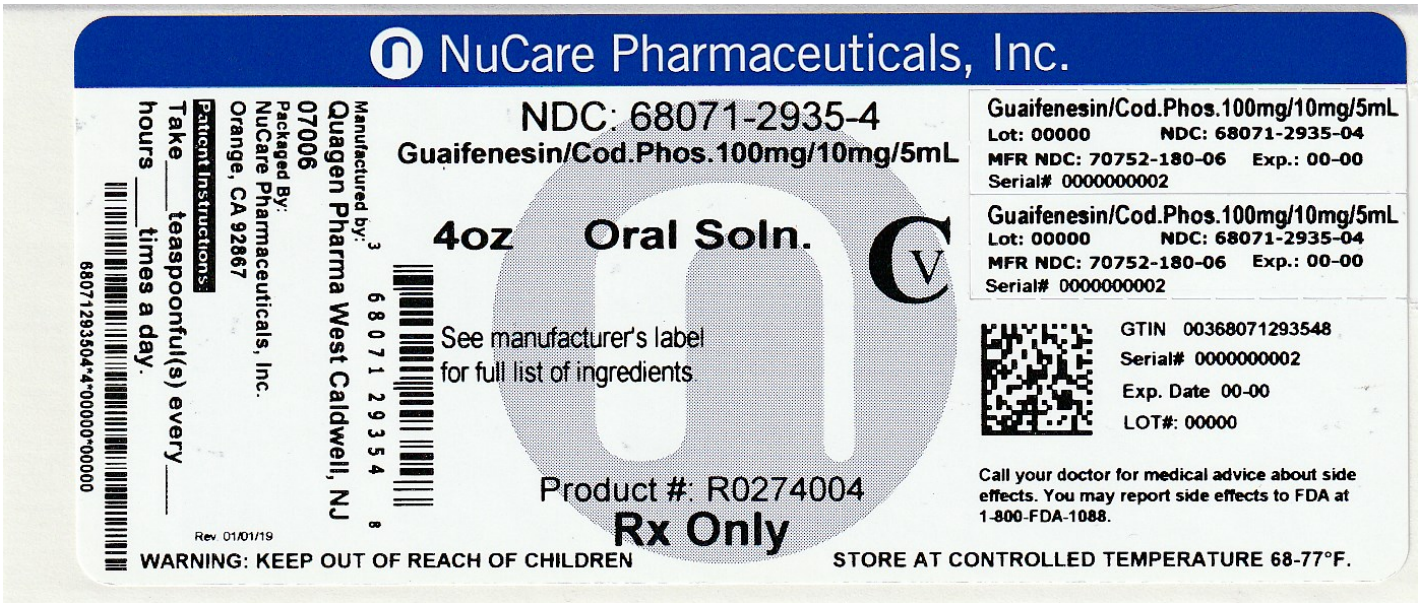
Caramel flavor, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, sodium benzoate, sodium saccharin, sorbitol.

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Manufactured by:
Quagen Pharmaceuticals LLC
West Caldwell, NJ 07006

MADE IN USA

PRINCIPAL DISPLAY PANEL



GUAIFENESIN AND CODEINE PHOSPHATE

guaifenesin and codeine phosphate solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-2935(NDC:70752-180)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CARAMEL, CHERRY, PEPPERMINT	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2935-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/23/2022	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2935)

Revised: 2/2023 NuCare Pharmaceuticals,Inc.