CODITUSSIN AC- codeine phosphate and guaifenesin syrup
Glendale 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.

Coditussin AC

Drug Facts

Active ingredients (in each teaspoonful)	***Purpose***
Codeine Phosphate* 10 mg	Antitussive (cough suppressant)
Guaifenesin 200 mg	Expectorant

* **(Warning: May be habit-forming)**

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

Warnings

Do not exceed recommended dosage.

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 do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- chronic pulmonary disease or shortness of breath, or children who are taking other drugs
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition
- new symptoms occur
- product may cause or aggravate constipation

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

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

Take this medication with a full glass of water after each dose to help loosen mucus in the lungs.

Adults and children 12 years of age and over:	2 teaspoonfuls every 4 hours, not to exceed 12 teaspoons in 24 hours
Children 6 to under 12 years of age:	1 teaspoonful every 4 hours, not to exceed 6 teaspoons in 24 hours
*Children under 6 years of age:	Consult a doctor

* Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

Other information

Store at 59°-86°F (15°-30°C) [see USP for Controlled Room Temperature]

Inactive ingredients

Citric Acid, Cotton Candy Flavor, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

Questions? Comments?

To report a serious adverse event or obtain product information, Call 1-630-530-7000.

Distributed by:

Glendale Inc

Villa Park, IL 60181

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 70147-616-16

Coditussin
AC

Expectorant
Cough Suppressant

CV

Each teaspoonful for oral administration contains:

Codeine Phosphate* 10 mg
*(Warning: May be habit-forming)

Guaifenesin 200 mg

SUGAR FREE / DYE FREE
ALCOHOL FREE

Cotton Candy Flavored Liquid

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

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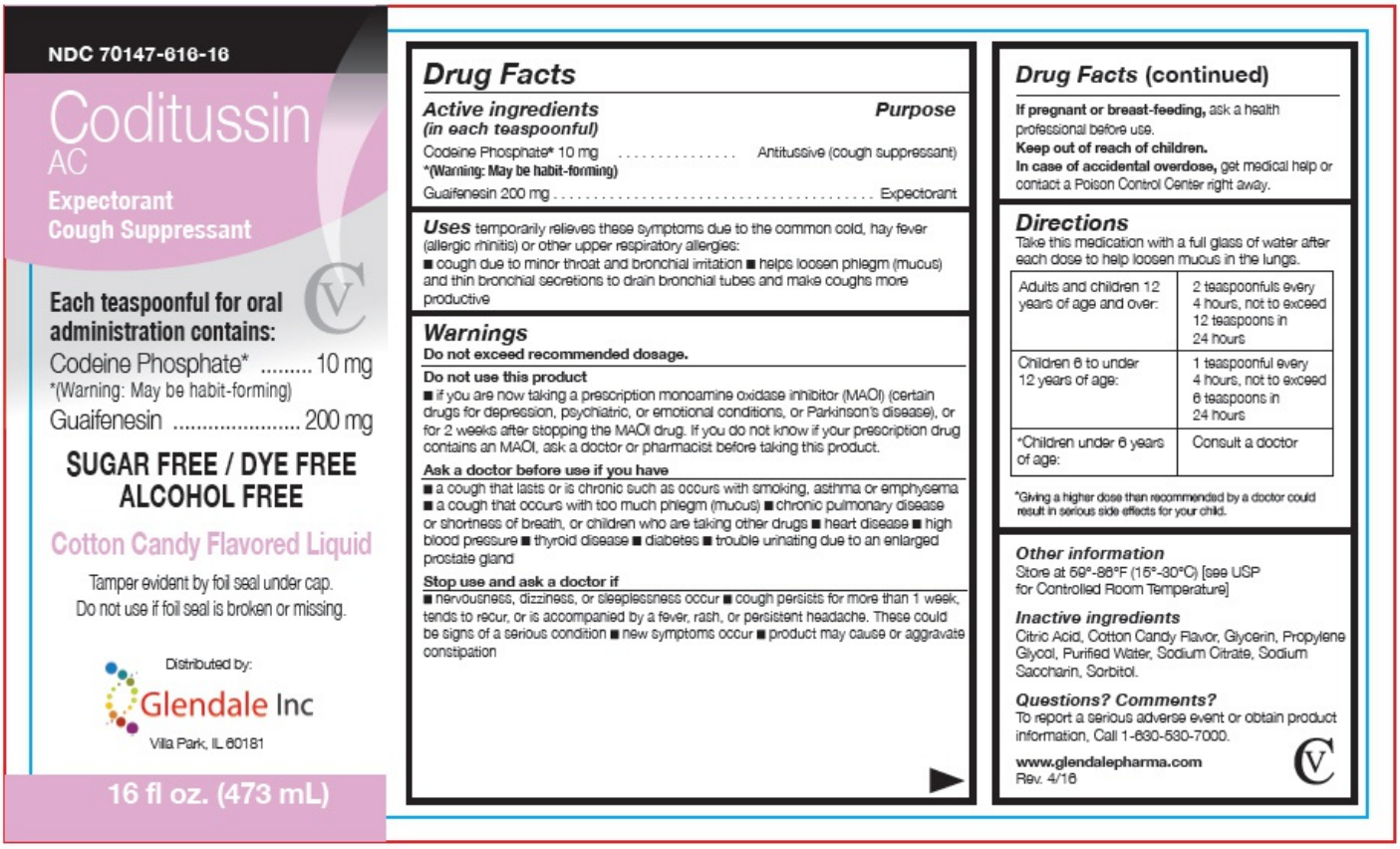
Villa Park, IL 60181

16 fl oz. (473 mL)



CODITUSSIN AC

codeine phosphate and guaifenesin syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70147-313
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL
		200 mg

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70147-313-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/01/2016	

Labeler - Glendale Inc (079987961)

Revised: 5/2016 Glendale Inc