CODITUSSIN DAC- codeine phosphate, guaifenesin, and pseudoephedrine hydrochloride 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 DAC

Drug Facts

Active ingredients (in each teaspoonful)	*Purpose*
Codeine Phosphate* 10 mg	Antitussive (cough suppressant)
Guaifenesin 200 mg	Expectorant
PseudoephedrineHydrochloride 30 mg	Nasal Decongestant

* **(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
- reduces swelling of nasal passages

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, chronic bronchitis 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

When using this product

- may cause or aggravate constipation

Stop use and ask a doctor if

- cough or nasal congestion 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
- nervousness, dizziness, or sleeplessness occur
- new symptoms occur

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

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	2 teaspoonfuls every 4 to 6 hours, not to exceed 8 teaspoons in a 24 hour period
Children 6 to under 12 years of age:	1 teaspoonfuls every 4 to 6 hours, not to exceed 8 teaspoons in a 24 hour period
*Children under 6 years of age:	Consult a doctor

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 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, Glycerin, Grape Flavor, 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 70147-414-16

Coditussin
DAC

Expectorant
Cough Suppressant
Nasal Decongestant

CV

Each teaspoonful for oral administration contains:

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

Guaifenesin 200 mg

Pseudoephedrine HCl 30 mg

SUGAR FREE / DYE FREE
ALCOHOL FREE / GLUTEN FREE

Grape Flavored Liquid

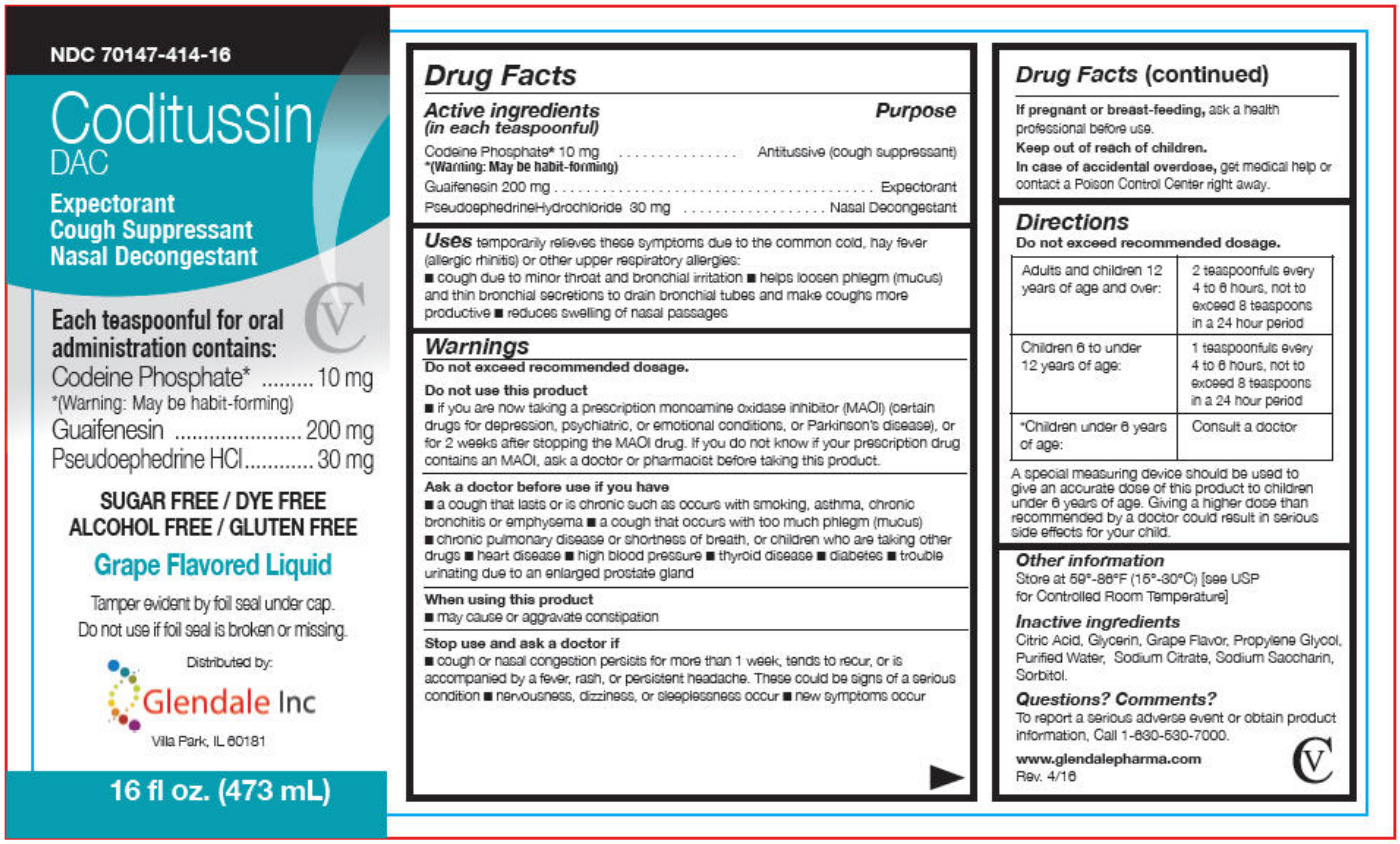
Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

Distributed by:

Glendale Inc

Villa Park, IL 60181

16 fl oz. (473 mL)



CODITUSSIN DAC

codeine phosphate, guaifenesin, and pseudoephedrine hydrochloride syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70147-414

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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 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:70147-414-16	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