

**CODAR GF- codeine phosphate, guaifenesin liquid**  
**Respa 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.*

-----

**Codar GF**

**Drug Facts**

**Active ingredients**

**(in each 5 mL teaspoonful)**

Codeine Phosphate\* 8 mg

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

Guaifenesin 200 mg

**Purpose**

Antitussive (Cough Suppressant)

Expectorant

**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 the 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 (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls 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 15°- 30°C (59°- 86°F)

**Inactive ingredients**

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

**Questions? Comments?**

Call (630) 543-3333

**Rx Only**

**CV**

Manufactured for:

**RESPA  
PHARMACEUTICALS, INC.**  
Addison, IL 60101

**Product Packaging**

The packaging below represents the labeling currently used:

Principal display panel and side panel for 473 mL label:

NDC 60575-616-16

---

Codar GF

Expectorant / Cough Suppressant

---

CV

Each 5 mL (one teaspoonful) for oral administration contains:

Codeine Phosphate\*.....8 mg

\*(Warning: May be habit-forming)

Guaifenesin.....200 mg

Cotton Candy Flavor

Rx Only

RESPA  
PHARMACEUTICALS, INC.  
Addison, IL 60101

16 fl oz. (473 mL)

SEE ATTACHED PRODUCT INSERT FOR COMPLETE DOSING INFORMATION.

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

Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Store at controlled room temperature, 15°-30°C (59°- 86°F).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:  
Respa Pharmaceuticals  
Addison, IL 60101

Rx Only

SEE ATTACHED PRODUCT INSERT FOR COMPLETE DOSING INFORMATION.

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

Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Store at controlled room temperature, 15°-30°C (59°-86°F).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:  
Respa Pharmaceuticals  
Addison, IL 60101

Rx Only

Rev. 05/11



NDC 60575-616-16

# Codar® GF

Expectorant • Cough Suppressant



Each 5 mL (one teaspoonful) for oral administration contains:  
Codeine Phosphate\* ..... 8 mg  
\*(Warning: May be habit-forming)  
Guaifenesin ..... 200 mg

Cotton Candy Flavor

Rx Only

**RESPA**  
PHARMACEUTICALS, INC.  
Addison, IL 60101

16 fl. oz. (473 mL)

## Drug Facts Lift Here

Active ingredients	Purpose
<i>(in each 5 mL teaspoonful)</i>	
Codeine Phosphate* 8 mg	..... Anthussive (Cough Suppressant)
*(Warning: May be habit-forming)	
Guaifenesin 200 mg	..... Expectorant

**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

**Drug Facts (continued)**

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 the 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 (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls 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 15° - 30°C (59° - 86°F)

**Drug Facts (continued)**

**Inactive ingredients**  
Bitter Mask, Citric Acid, Cotton Candy Flavor, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

**Questions? Comments?**  
Call (630) 543-3333

Rx Only



Manufactured for:



Addison, IL 60101

## CODAR GF

codeine phosphate, guaifenesin liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60575-616
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	CV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Codeine Phosphate</b> (UNII: GSL05Y1MN6) (Codeine - UNII:Q830PW7520)	Codeine Phosphate	8 mg in 5 mL
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Citric Acid</b> (UNII: 2968PHW8QP)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	

<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Citrate</b> (UNII: 1Q73Q2JULR)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Sorbitol</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	COTTON CANDY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60575-616-16	473 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/21/2011	

**Labeler** - Respa Pharmaceuticals, Inc. (883901019)

Revised: 6/2011

Respa Pharmaceuticals, Inc.