# CODAR AR- chlorpheniramine maleate, codeine phosphate 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.

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#### Codar AR

Drug Facts
Active ingredients
(in each 5 mL teaspoonful)
Chlorpheniramine Maleate 2 mg
Codeine Phosphate\* 8 mg
\*(Warning: May be habit-forming)

#### **Purpose**

Antihistamine Antitussive (Cough Suppressant)

#### Uses

temporarily relieves runny nose, sneezing, itching of the nose or throat, and itchy watery eyes due to hay fever or other upper respiratory allergies (allergic rhinitis). Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants and helps you cough less.

#### **Warnings**

Do not exceed recommended dosage.

#### Do not take this product, unless directed by a doctor before use if you have

- a persistent or chronic cough such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- a chronic pulmonary disease, shortness of breath, or children who are taking other drugs
- a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma
- difficulty in urination due to enlargement of the prostate gland.

#### Ask a doctor before use if you are

taking sedatives or tranquilizers

#### When using this product

- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

#### Stop use and ask a doctor if

• 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.
- may cause or aggravate constipation.

#### If pregnant or breast-feeding,

ask a health professional before use.

### Keep this and other drugs 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 recommended dosage.

	2 teaspoonfuls (10 mL) every 4-6 hours, not to exceed 12 teaspoonfuls in a 24 hour period.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4-6 hours, not to exceed 6 teaspoonfuls 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 effects for your child.

#### Other information

Store at 15°- 30°C (59°- 86°F)

#### **Inactive ingredients**

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

#### **Questions? Comments?**

Call (630) 543-3333

#### Rx Only

 $\mathbf{CV}$ 

Manufactured for:

# RESPA PHARMACEUTICALS, INC.

Addision, IL 60101

### **Product Packaging**

The packaging below represents the labeling currently used:

Principal display panel and side panel for 473 mL label:

NDC 60575-212-16

#### Codar AR

#### **Antihistamine / Cough Suppressant**

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

CV

**Apple Flavor** 

**Rx Only** 

RESPA PHARMACEUTICALS, INC.

Addision, 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**

Rev. 05/11

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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).

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Manufactured for: Respa Pharmaceuticals Addison, IL 60101

Rx Only

Rev. 05/11



NDC 60575-212-16

### Codar° A

Antihistamine • Cough Suppressant

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

Apple Flavor

Rx Only



16 fl oz. (473 mL)

### Drug Facts Lift Here

Active ingredients Purpose 

Uses temporarily relieves runny nose, sneezing, itching of the nose or throat, and Itchy, watery eyes due to hay fever or other upper respiratory allergies (allergic rhinitis). Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants and helps you cough less.

#### Warnings

Do not exceed recommended dosage.

Do not take this product, unless directed by a doctor before use if you have •a persistent or chronic cough such as

- occurs with smoking, asthma or emphysema •a cough that occurs with too much
- phlegm (mucus)
- ■a chronic pulmonary disease, shortness of breath, or children who are taking other drugs
- a breathing problem such as emphysema or chronic bronchitis, or if you have daucoma
- difficulty in urination due to enlargement of the prostate gland.

Ask a doctor before use if you are taking sedatives or tranquilizers

#### Drug Facts (continued)

#### When using the product

- may cause marked drowsiness
- ■avoid alcoholic beverages
- ■alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

excitability may occur, especially in children

#### Stop use and ask a doctor if

■ 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.

may cause or aggravate constipation.

If pregnant or breast-feeding, ask a health

professional before use. Keep this and other drugs out of the reach of children. In case of overdose, get medical help or contact a Polson Control Center right

#### Directions

Do not exceed recommended dosage.

Adults and Children 12 years of age and over: 2 teaspoonfuls (10 mL) every 4-6 hours, not to exceed 12 teaspoonfuls in a 24 hour period. Children 6 to under 1 teaspoonful (5 mL) every 4-6 hours, not to 12 years of age: exceed 6 teaspoonfuls in a 24 hour period. Children under 6 Consult a doctor. years of age:

A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. GMing a higher dose than recommended by a doctor could result in serious effects for your child.

#### Drug Facts (continued)

Other information Store at 15°-30°C (59°-86°F)

*Inactive ingredients* Apple Flavor, Citric Acid, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbifol.

Questions? Comments? Call (630) 543-3333

#### Rx Only



Manufactured for:



Addison, IL 60101

#### CODAR AR

chlorpheniramine maleate, codeine phosphate liquid

#### **Product Information** HUMAN OTC DRUG NDC:60575-212 Product Type Item Code (Source) ORAL CV**Route of Administration DEA Schedule**

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine Maleate	2 mg in 5 mL	
Codeine Phosphate (UNII: GSL05Y1MN6) (Codeine - UNII:Q830PW7520)	Codeine Phosphate	8 mg in 5 mL	

Inactive Ingredients			
I	ngredient Name	Strength	
Citric Acid (UNII: 2968PHW8QP)			

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

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	APPLE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60575-212-16	473 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/20/2011	

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

Revised: 6/2011 Respa Pharmaceuticals, Inc.