

CODAR D- codeine phosphate, pseudoephedrine hydrochloride liquid
Respa Pharmaceuticals

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 D

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Codeine Phosphate* 8 mg

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

Pseudoephedrine Hydrochloride 30 mg

Purpose

Cough Suppressant

Nasal Decongestant

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
- nasal congestion
- 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 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 mellitus
- difficulty in urination due to an enlarged prostate gland

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

When using this product

- may cause or aggravate constipation

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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.
- new symptoms occur

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

Keep out of reach of children.

In case of 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 (10 mL) every 4-6 hours, not to exceed 8 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 4 teaspoonfuls in a 24 hour period.
Children under 6 years of age:	Not recommended for use.

Other information

Store at 15°- 30°C (59°- 86°F)

Inactive ingredients

Berry Flavor, Citric Acid, 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 pane for 473 mL label:

NDC 60575-515-16

Codar[®] D

Cough Suppressant / Nasal Decongestant

CV

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

Codeine Phosphate*.....8 mg
Pseudoephedrine HCl.....30 mg

Berry 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

Rev. 06/11

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Manufactured for:
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Addison, IL 60101

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Rev. 06/11



NDC 60575-515-16

Codar[®] D

Cough Suppressant • Nasal Decongestant



Each 5 mL (one teaspoonful) for oral administration contains:
Codeine Phosphate* 8 mg
*(Warning: May be habit-forming)
Pseudoephedrine HCl 30 mg

Berry Flavor

Rx Only

RESPA[®]

PHARMACEUTICALS, INC.

Addison, IL 60101

16 fl oz. (473 mL)

Drug Facts Lift Here


Active ingredients Purpose (in each 5 mL teaspoonful)
Codeine Phosphate* 8 mg
..... Antitussive (Cough Suppressant)
*(Warning: May be habit-forming)
Pseudoephedrine Hydrochloride 30 mg
..... Nasal Decongestant

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 ■ nasal congestion
■ 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 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 mellitus ■ difficulty in urination due to an enlarged prostate gland

<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p>When using this product</p> <ul style="list-style-type: none"> may cause or aggravate constipation <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> nervousness, dizziness, or sleeplessness occur 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. new symptoms occur <p>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.</p> <p>Directions</p> <p>Do not exceed recommended dosage.</p> <table border="1"> <tr> <td>Adults and Children 12 years of age and over:</td> <td>2 teaspoonfuls (10 mL) every 4-6 hours, not to exceed 8 teaspoonfuls in a 24 hour period.</td> </tr> <tr> <td>Children 6 to under 12 years of age:</td> <td>1 teaspoonful (5 mL) every 4-6 hours, not to exceed 4 teaspoonfuls in a 24 hour period.</td> </tr> <tr> <td>Children under 6 years of age:</td> <td>Not recommended for use.</td> </tr> </table> <p>Other information</p> <p>Store at 15°-30°C (59°-86°F)</p>	Adults and Children 12 years of age and over:	2 teaspoonfuls (10 mL) every 4-6 hours, not to exceed 8 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 4 teaspoonfuls in a 24 hour period.	Children under 6 years of age:	Not recommended for use.	<p>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>Berry Flavor, Citric Acid, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.</p> <p>Questions? Comments?</p> <p>Call (630) 543-3333</p> <p>Rx Only</p> <p></p> <p>Manufactured for:</p> <p>RESPA PHARMACEUTICALS, INC.</p> <p>Addison, IL 60101</p>
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CODAR D

codeine phosphate, pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60575-515
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Codeine Phosphate (UNII: GSL05Y1MN6) (Codeine - UNII:Q830PW7520)	Codeine Phosphate	8 mg in 5 mL
Pseudoephedrine Hydrochloride (UNII: 6 V9 V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid (UNII: 2968PHW8QP)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0K00R)	

Sodium Citrate (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60575-515-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/13/2011	

Labeler - Respa Pharmaceuticals (883901019)

Revised: 7/2011

Respa Pharmaceuticals