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

 \mathbf{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

 $Codar^{\mathbb{R}} \overline{D}$

Cough Suppressant / Nasal Decongestant

 \mathbf{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 Rev. 06/11

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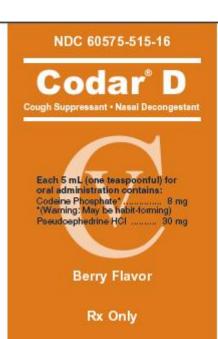
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Rx Only

Rev. 06/11







16 fl oz. (473 mL)

Drug Facts

Lift Here

Active ingredients Pur (in each 5 mL teaspoonful) Purpose

..... Nasal Decongestan

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

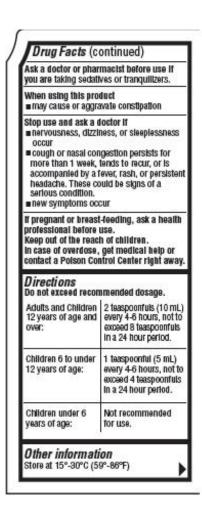
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Ask a doctor before use if you have •a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema ■a cough that occurs with

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chronic pulmonary disease or shortness of
breath or children who are taking other drugs mheart disease mhigh blood pressure #thyroid disease #diabetes melitus adifficulty in urination due to an enlarged prostate gland





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 Sche dule | 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:7CUC9 DDI9F) | Pseudo ephedrine Hydro chlo ride | 30 mg in 5 mL | |

| Inactive Ingredients | | |
|-------------------------------------|----------|--|
| Ingredient Name | Strength | |
| Citric Acid (UNII: 2968 PHW8 QP) | | |
| Glycerin (UNII: PDC6A3C0OX) | | |
| 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 | 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