

**PRO-RED AC- codeine phosphate, dexchlorpheniramine maleate, phenylephrine hydrochloride syrup**  
**Pro-Pharma, LLC**

*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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**PRO-RED AC SYRUP**

**Drug Facts**

**Active ingredients**

**(in each 5 mL teaspoonful)**

Codeine Phosphate 9 mg

**\*(WARNING: MAY BE HABIT-FORMING)**

Dexchlorpheniramine Maleate 1 mg

Phenylephrine Hydrochloride 5 mg

**Purpose**

Antitussive

Antihistamine

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
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

**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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

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

**When using this product**

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

**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. A persistent cough may be a sign of a serious condition.
- new symptoms occur

**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.

**Directions**

**Do not exceed recommended dosage.**

Adults and children 12 years of age and older:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 6 doses in a 24 hours.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 doses in a 24 hours.
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)

**Inactive ingredients**

Citric Acid, Cotton Candy Flavor, FD&C Red #40, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol

**Questions? Comments?**

Serious side effects associated with use of this product may be reported to this number. 1-660-665-0084

(8 a.m. to 5 p.m.)

CV

**Product Packaging**

Principal display panel and side panel for 473 mL label:

**NDC #66594-499-16**

**CV**

**PRO-RED AC**

**SYRUP**

**ALCOHOL FREE / SUGAR FREE / GLUTEN FREE**

**ANTITUSSIVE / ANTIHISTAMINE / NASAL DECONGESTANT**

Each teaspoonful (5 mL) contains:

CODEINE PHOSPHATE.....9 mg

**\*(WARNING: MAY BE HABIT-FORMING)**

□ DEXCHLORPHENIRAMINE

MALEATE.....1 mg

PHENYLEPHRINE

HYDROCHLORIDE.....5 mg

Cotton Candy Flavor

16 FL. OZ. (473 mL)

PRO-PHARMA LLC

"NEW FORMULATION"

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

**THIS BOTTLE NOT TO BE DISPENSED TO CONSUMER.**

Dispense in a tight, light-resistant container with a child-resistant cap.

Manufactured by:

Pernix Manufacturing, LLC

Houston, TX 77099

Distributed for:

Pro-Pharma, LLC

Kirkville, MO 63501

Rev. 09/13



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ANTITUSSIVE • ANTIHISTAMINE • NASAL DECONGESTANT

Each teaspoonful (5mL) contains:

CODEINE PHOSPHATE ..... 9 mg  
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DEXCHLORPHENIRAMINE  
MALEATE ..... 1 mg

PHENYLEPHRINE  
HYDROCHLORIDE ..... 5 mg

Cotton Candy Flavor

16 FL. OZ. (473 mL)

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"NEW FORMULATION"

## Drug Facts Lift Here

### Active ingredients Purpose (in each 5 mL teaspoonful)

Codeine Phosphate 9 mg ..... Antitussive  
\*(WARNING: MAY BE HABIT-FORMING)  
Dexchlorpheniramine  
Maleate 1 mg ..... Antihistamine  
Phenylephrine  
Hydrochloride 5 mg ..... Nasal Decongestant

### Uses

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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

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ a cough that occurs with too much phlegm (mucus)</li> <li>■ chronic pulmonary disease or shortness of breath, or children who are taking other drugs</li> <li>■ heart disease ■ high blood pressure</li> <li>■ thyroid disease ■ diabetes</li> <li>■ trouble urinating due to an enlarged prostate gland</li> <li>■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma</li> </ul> <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ may cause or aggravate constipation</li> <li>■ excitability may occur, especially in children</li> <li>■ may cause marked drowsiness</li> <li>■ avoid alcoholic drinks</li> <li>■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ nervousness, dizziness, or sleeplessness occur</li> <li>■ cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.</li> <li>■ new symptoms occur</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ▶</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> Do not exceed recommended dosage.</p> <table border="1"> <tr> <td>Adults and children 12 years of age and over:</td> <td>2 teaspoonsful (10 mL) every 4 hours, not to exceed 6 doses in 24 hours.</td> </tr> <tr> <td>Children 6 to under 12 years of age:</td> <td>1 teaspoonful (5 mL) every 4 hours, not to exceed 6 doses in 24 hours.</td> </tr> <tr> <td>Children under 6 years of age:</td> <td>Consult a doctor.</td> </tr> </table> <p>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.</p> <p><b>Other information</b> Store at 59° - 86° F (15° - 30° C)</p> <p><b>Inactive ingredients</b> Citric Acid, Cotton Candy Flavor, FD&amp;C Red #40, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.</p> <p><b>Questions? Comments?</b> Serious side effects associated with use of this product may be reported to this number: 1-866-665-0084 (8 a.m. to 5 p.m.)</p> 	Adults and children 12 years of age and over:	2 teaspoonsful (10 mL) every 4 hours, not to exceed 6 doses in 24 hours.	Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 doses in 24 hours.	Children under 6 years of age:	Consult a doctor.
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## PRO-RED AC

codeine phosphate, dexchlorpheniramine maleate, phenylephrine hydrochloride syrup

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66594-499
<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 ANHYDROUS - UNII:UX6OWY2V7J)	Codeine Phosphate	9 mg in 5 mL
<b>DEXCHLORPHENIRAMINE MALEATE</b> (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N)	DEXCHLORPHENIRAMINE MALEATE	1 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	

<b>Water</b> (UNII: 059QF0K00R)	
<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:66594-499-16	473 mL in 1 BOTTLE		
2	NDC:66594-499-01	30 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/30/2013	

**Labeler** - Pro-Pharma, LLC (781088146)

**Registrant** - Pernix Manufacturing, LLC (078641814)

### Establishment

Name	Address	ID/FEI	Business Operations
Pernix Manufacturing, LLC dba Great Southern Laboratories		078641814	manufacture(66594-499)