

PRO-CLEAR AC- codeine phosphate and pyrilamine maleate 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.

PRO-CLEAR AC SYRUP

Drug Facts

Active ingredients

(in each 5 mL teaspoonful)

Codeine Phosphate* 9 mg

*WARNING: May be habit forming.

Pyrilamine Maleate 8.33 mg

Purpose

Antitussive

Antihistamine

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

Warnings

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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating 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
- 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

- a cough 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 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 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.

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, 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. Call 1-660-665-0084 (8 a.m. to 5 p.m.)

CV

Product Packaging:

The packaging below represents the labeling currently used.

Principal display panel and side panel for 473 mL label:

NDC # 66594-333-16

CV

**PRO-CLEAR AC
SYRUP**

SUGAR FREE · DYE FREE · ALCOHOL FREE · GLUTEN FREE

ANTITISSIVE · ANTIHISTAMINE

Each teaspoonful (5 mL) contains:

CODEINE PHOSPHATE*.....9 mg
*(WARNING: MAY BE HABIT-FORMING)
PYRILAMINE MALEATE.....8.33 mg

Cotton Candy Flavor

16 FL. OZ. (473 mL)

PRO-PHARMA LLC

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

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

THIS BOTTLE IS NOT TO BE DISPENSED TO THE CONSUMER.

Manufactured by:
Great Southern Laboratories,
Houston, TX 77099

Distributed for:
Pro-Pharma, LLC
Kirksville, MO 63501

Rev. 10/11



NDC # 66594-333-16



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**PRO-CLEAR AC**

codeine phosphate and pyrilamine maleate syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66594-333
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	9 mg in 5 mL
Pyrilamine Maleate (UNII: R35D29L3ZA) (Pyrilamine - UNII:HPE317O9TL)	Pyrilamine Maleate	8.33 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid (UNII: 2968PHW8QP)	
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	COTTON CANDY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66594-333-01	30 mL in 1 BOTTLE		
2	NDC:66594-333-16	473 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/08/2008	

Labeler - Pro-Pharma LLC (781088146)

Registrant - Great Southern Laboratories (056139553)

Establishment			
Name	Address	ID/FEI	Business Operations
Great Southern Laboratories		056139553	manufacture