PRO-CHLO - chlophedianol hydrochloride, phenylephrine hydrochloride, pyrilamine maleate liquid
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-CHLO LIQUID

Drug Facts
Active ingredients
(in each 5 mL teaspoonful)
Chlophedianol HCl 12.5 mg
Phenylephrine HCl 5 mg
Pyrilamine Maleate 12.5 mg

Purpose
Antitussive
Nasal Decongestant
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
- nasal congestion
- reduces swelling of nasal passages
- runny nose
- sneezing
- itching of the nose or throat
- itchy, water eyes

Warnings
Do not exceed recommended dosage.

Do not use this product

- if you are now taking a prescription monoamine oxidase inhibibor (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)
- 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
- 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 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 6 hours, not to exceed 8 teaspoonfuls in 24 hours
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 6 hours, not to exceed 4 teaspoonfuls in 24 hours
Children under 6 years of age:	Consult a doctor.

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

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

Questions? Comments?
Call 1-660-665-0084

Product Packaging

The packaging below represents the labeling currently used:

Principal display panel and side panel for 473 mL label:

NDC #66594-321-16

PRO-CHLO
LIQUID

ALCOHOL FREE·GLUTEN FREE·SUGAR FREE

ANTITUSSIVE · NASAL DECONGESTANT
· ANTIHISTAMINE

Each teaspoonful (5 mL) contains:

CHLOPHEDIANOL HCL.....12.5 mg
PHENYLEPHRINE HCL.....5 mg
PYRILAMINE MALEATE.....12.5 mg

Cotton Candy Flavor

PATENT PENDING

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.

Patent Pending

Manufactured by:
Great Southern Laboratories,
Houstin, TX 77099

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

Iss. 10/11

N 3 66594-321-16 8

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Lift Here

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Phenylephrine HCl 5 mg	Nasal Decongestant
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PRO-CHLO

chlophedianol hydrochloride, phenylephrine hydrochloride, pyrilamine maleate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66594-321
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chlophedianol Hydrochloride (UNII: 69QQ58998Y) (Chlophedianol - UNII:42C50P12AP)	Chlophedianol Hydrochloride	12.5 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 5 mL
Pyrilamine Maleate (UNII: R35D29L3ZA) (Pyrilamine - UNII:HPE317O9TL)	Pyrilamine Maleate	12.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (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:66594-321-16	473 mL in 1 BOTTLE		
2	NDC:66594-321-01	30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/12/2011	

Labeler - Pro-Pharma, LLC (781088146)

Registrant - Great Southern Laboratories (056139553)

Establishment

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

Revised: 11/2011 Pro-Pharma, LLC