

**CLOPHED - chlophedianol hydrochloride, guaifenesin, phenylephrine hydrochloride liquid**  
**Portal Pharmaceutical**

*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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**Chlophed**

**Drug Facts**

**Active ingredients**

**(in each 5 mL teaspoonful)**

***Chlophedianol Hydrochloride 12.5 mg***

***Guaifenesin 100 mg***

***Phenylephrine Hydrochloride 5 mg***

**Cough Suppressant**

**Expectorant**

**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
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of the 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)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

**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 the reach of children.**

**In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.**

**Directions**

**Do not exceed recommended dosage.**

Adults and children 12 years of age and over:	2 teaspoonfuls every 6 to 8 hours, not to exceed 8 teaspoonfuls in a 24 hour period
Children 6 to under 12 years of age:	1 teaspoonful every 6 to 8 hours, not to exceed 4 teaspoonfuls in a 24 hour period
Children under 6 years of age	Consult a doctor

**Other information**

Store at 59° - 86° F(15° - 30° C)

**Inactive ingredients**

Citric Acid, Glycerin, Orange Vanilla Flavor, propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, and Sorbitol.

**Questions? Comments?**

Call 1-787-832-6645

Serious side effects associated with this product may be reported to this number.

**Product Packaging:**

Packaging below represents the labeling currently used:

Principal display panel and side panel for 118 mL label:

**NDC 49963-630-04**

Clophed

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

Chlophedianol HCl.....12.5 mg  
Guaifenesin.....100 mg  
Phenylephrine HCl.....5 mg

# Cough Suppressant/Expectorant/Nasal Decongestant

Alcohol Free/Dye Free/Gluten Free/Sugar Free

4 fl oz (118 mL)

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

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

See package insert for full prescribing information.

Manufactured for:  
Portal Pharmaceutical  
Mayaguez, PR 00680

Rev. 10/09

Lot: P10042 Exp. Date: 05/2012

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.  
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**Cough Suppressant/  
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Nasal Decongestant**  
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4 fl oz (118 mL)

<b>Drug Facts</b>	
Lift Here for Drug Facts	
<b>Active ingredients (in each 5 mL teaspoonful)</b>	<b>Purpose</b>
Chlophedianol Hydrochloride 12.5 mg ...	Cough Suppressant
Guaifenesin 100 mg .....	Expectorant
Phenylephrine Hydrochloride 5 mg .....	Nasal Decongestant
<b>Uses</b> temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:	



**Drug Facts (continued)**

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**Drug Facts (continued)**

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## CLOPHED

chlorphedianol hydrochloride, guaifenesin, phenylephrine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49963-630
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Chlorphedianol Hydrochloride</b> (UNII: 69QQ58998 Y) (Chlorphedianol - UNII:42C50P12AP)	Chlorphedianol Hydrochloride	12.5 mg in 5 mL
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59 TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Citric Acid</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>	ORANGE, VANILLA	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49963-630-04	118 mL in 1 BOTTLE		
2	NDC:49963-630-15	15 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/28/2010	

**Labeler** - Portal Pharmaceutical (831005199)

Revised: 12/2010

Portal Pharmaceutical