# VANACOF AC- chlophedianol hcl, pyrilamine maleate liquid GM Pharmaceuticals, Inc.

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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#### VanaCof AC

# **Active Ingredients**

Each 30 mL contains:

Chlophedianol HCl .....12.5

Pyrilamine Maleate ......25

### **Purpose**

**Cough Suppressant** 

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

### **Warnings**

#### Do not exceed recommended dosage

# Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis

## Ask a doctor or pharmacist before use if you are

• taking sedatives or tranquilizers

#### When using this poduct

- do not use more than directed
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholics drinks
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

# Stop use and ask a doctor if:

- nervousness, dizziness or sleeplessnss occurs
- symptoms do not improve within 7 days, tend to recur, or are 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 professhional 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 take more than 4 doses in any 24-hour period.
- Do not exceed recommended dosage.
- Use enclosed dose cup
- Keep dosage cup with product

adults and children 12 years of age and over:	60 mL every 6-8 hours
children 6 to under 12 years of age:30	30 mLevery 6-8 hours
children under 6 years of age:	Do not use

#### Other information

- each 30 mL contains: Sodium 12 mg
- tamper evident: Do not use if foil seal under cap is broken or missing.
- read all product information before using
- store at room temperature 68-77°F (20-25°C)
- avoid excessive heat and humidity

# **Inactive Ingredients**

citric acid anhydrous, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol solution, sucralose

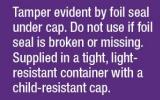
### **Questions or Comments?**

Call 1-888-535-0305 9 a.m. - 5 p.m. CST.

# Distributed by:

**GM** Pharmaceuticals

Arlington, TX 76015



Distributed by: GM Pharmaceuticals, Inc. Arlington, TX 76015 **Patent Pending** R030317



Each 30 mL contains: Chlophedianol Hydrochloride.....12.5 mg

Pyrilamine Maleate...... 25 mg

Cough Suppressant • Antihistamine

8 HOUR

# NON-NARCOTIC

Dye Free | Alcohol Free | Sugar Free | Gluten Free **Decongestant Free** 



8 fl. oz. (237 mL)

# **Drug Facts** Active ingredients (in each 30 mL)

Purpose

DSGS
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 - tichy, watery eyes
- tiching of the nose or throat

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

glaucoma difficulty in urination due to enlargement of the prostate gland cough that occurs with too much phlegm (muc a breathing problem such as emphysema or chemic hornolitis.

#### Drug Facts (continued)

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If pregnant or breast-feeding, ask a health professional before use.

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- children 6 to under 12 years of age: 30 mL every 6 to 8 hours

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## Drug Facts (continued)

Inactive ingredients
citric acid anhydrous, glycerin, propylene glycol,
purified water, sodium benzoate, sodium citrate
dihydrate, sorbitol solution, sucralose

Questions or comments? Call 1-888-535-0305 9 a.m. - 5 p.m. CST.



KEEP LEAFLET AFTER OPENING

#### VANACOF AC

chlophedianol hcl, pyrilamine maleate liquid

### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:58809-329

**Route of Administration** ORAL

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	25 mg in 30 mL
CHLO PHEDIANO L HYDRO CHLO RIDE (UNII: 69QQ58998Y) (CHLO PHEDIANO L - UNII: 42C50 P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	12.5 mg in 30 mL

### **Inactive Ingredients**

**Ingredient Name** Strength

ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

F	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1	NDC:58809-329-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2017			

<b>Marketing Info</b>	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	03/01/2017		

# Labeler - GM Pharmaceuticals, Inc. (793000860)

Revised: 3/2017 GM Pharmaceuticals, Inc.