

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.

VanaCof AC

Active Ingredients

Each 30 mL contains:

Chlophedianol HCl12.5

Pyrilamine Maleate25

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 product

- **do not use more than directed**
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic 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 sleeplessness 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 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 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 mL every 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

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.

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

NDC 58809-329-08

VanaCof[®]AC

Each 30 mL contains:
Chlophedianol Hydrochloride..... 12.5 mg
Pyrilamine Maleate..... 25 mg

Cough Suppressant • Antihistamine



NON-NARCOTIC

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



8 fl. oz. (237 mL)

<p>Drug Facts</p> <p>Active ingredients (in each 30 mL) Chlophedianol HCl 12.5 mg Cough Suppressant Pyrilamine Maleate 25 mg Antihistamine</p> <p>Purpose</p> <p>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</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are • taking sedatives or tranquilizers</p> <p>When using this product • do not use more than directed • marked drowsiness may occur • alcohol, sedatives, and tranquilizers may increase drowsiness • avoid alcoholic drinks • be careful when driving a motor vehicle or operating machinery • excitability may occur, especially in children</p> <p>Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness 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</p> <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>Drug Facts (continued)</p> <p>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</p> <table border="1"> <tr> <td>adults and children 12 years of age and over:</td> <td>60 mL every 6 to 8 hours</td> </tr> <tr> <td>children 6 to under 12 years of age:</td> <td>30 mL every 6 to 8 hours</td> </tr> <tr> <td>children under 6 years of age:</td> <td>Do not use.</td> </tr> </table> <p>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</p>	adults and children 12 years of age and over:	60 mL every 6 to 8 hours	children 6 to under 12 years of age:	30 mL every 6 to 8 hours	children under 6 years of age:	Do not use.	<p>Drug Facts (continued)</p> <p>Inactive ingredients citric acid anhydrous, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol solution, sucralose</p> <p>Questions or comments? Call 1-888-535-0305 9 a.m. - 5 p.m. CST.</p> <p>Distributed by: GM Pharmaceuticals, Inc. Arlington, TX, 76015</p> <p>KEEP LEAFLET AFTER OPENING</p>	
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VANACOF AC

chlophedianol hcl, pyrilamine maleate liquid

Product Information

Product Type	HUMAN OTC DRUG	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
CHLOPHEDIANOL HYDROCHLORIDE (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
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ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

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

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.