VANACOF- chlophedianol hydrochloride, dexchlorpheniramine maleate, and pseudoephedrine hydrochloride 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

Drug Facts

Active ingredients (in each 5 mL teaspoonful)

Chlophedianol Hydrochloride 12.5 mg

Dexchlorpheniramine Maleate 1 mg

Pseudoephedrine Hydrochloride 30 mg

Purpose

Cough Suppressant

Antihistamine

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
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of 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)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- heart disease
- high blood pressure
- thyroid disease
- diabetes

Ask a doctor 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
- use caution 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 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 every 6 hours, not to exceed 8 teaspoonfuls in 24 hours.
children 6 to under 12 years of age:	1 teaspoonful every 6 hours, not to exceed 4 teaspoonfuls in 24 hours.
children under 6 years of age:	consult a doctor.

Other information

Store at room temperature of 68°-86°F (20°-30°C) with excursions of 59°-86°F (15°-30°C)

Inactive ingredients

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

Questions or Comments?

Call 1-888-535-0305 9a.m. – 5p.m. CST

PRINCIPAL DISPLAY PANEL

NDC 58809-999-01
VanaCof®

Each 5 mL (1 TEASPOONFUL) CONTAINS:
Chlophedianol Hydrochloride ..... 12.5 mg
Dexchlorpheniramine Maleate ..... 1 mg
Pseudoephedrine Hydrochloride 30mg

Drug Facts (continued)

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58809-999
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
DEXCHLORPHENIRAMINE MALEATE (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N)	DEXCHLORPHENIRAMINE MALEATE	1 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	TUTTI FRUTTI	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-999-02	12 in 1 TRAY	04/22/2008	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58809-999-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/22/2008	

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 1/2022 GM Pharmaceuticals, INC