VANACOF- chlophedianol hydrochloride, dexchlorpheniramine maleate, and pseudoephedrine hydrochloride liquid GM Pharmaceuticals, INC

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:
 - runny nose
 - sneezing
 - itching of the nose or throat
 - itchy, watery eyes
 - nasal congestion
 - reduces swelling of nasal passages
- cough due to minor throat and bronchial irritation

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
- trouble urinating due to an enlarged prostate gland
- glaucoma
- 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
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic drinks
- 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 | 2 teaspoonfuls every 6 hours, not to |
|-----------------------------------------|------------------------------------------------------------------------|
| over: | exceed 8 teaspoonfuls in 24 hours. |
| | 1 teaspoonful every 6 hours, not to exceed 4 teaspoonfuls in 24 hours. |
| children under 6 years of age: | consult a doctor. |

Other information

this package is child resistant

 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

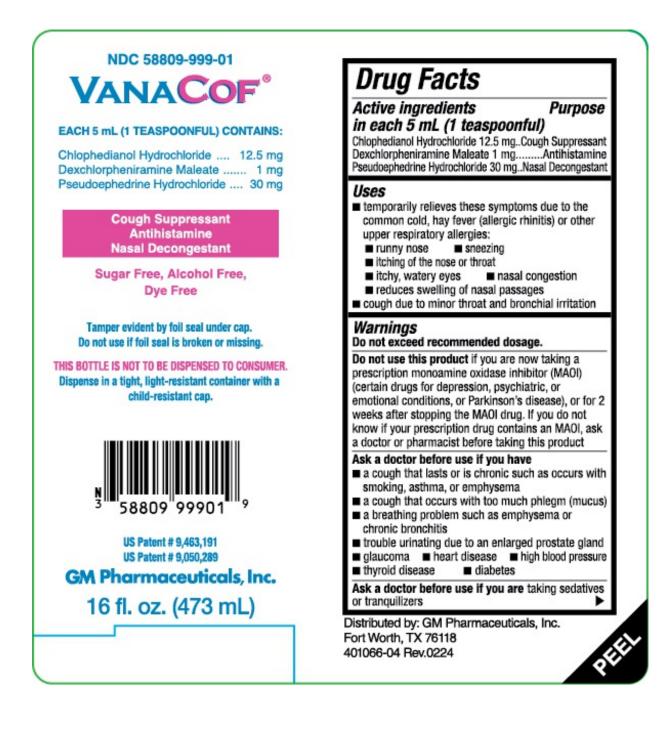
Questions or Comments?

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 (continu | ued) | | |
|-----------------------------------------------------------------|------------------------------------------|--|--|
| When using this produc | t | | |
| excitability may occur, | | | |
| may cause marked dro | | | |
| alcohol, sedatives, and | tranquilizers may increase the | | |
| drowsiness effect | | | |
| avoid alcoholic drinks | | | |
| use caution when driving a motor vehicle or operating machinery | | | |
| Stop use and ask a doc | | | |
| nervousness, dizziness | | | |
| | tion persists for more than 1 week, | | |
| | companied by a fever, rash or persistent | | |
| | cough may be a sign of a serious | | |
| condition. | | | |
| new symptoms occur | eding, ask a health professional | | |
| before use. | eding, ask a nearth professional | | |
| | ildren. In case of overdose, get | | |
| medical help or contact a | Poison Control Center right away. | | |
| D' | | | |
| Directions ■ mL= milliliter | | | |
| Age | Dose | | |
| adults and children 12 | 2 teaspoonfuls (10 mL) every 6 hours, | | |
| years of age and over: | not to exceed 8 teaspoonfuls | | |
| years of age and over. | (40 mL) in 24 hours. | | |
| children 6 to under 12 | 1 teaspoonful (5 mL) every 6 hours, | | |
| years of age: | not to exceed 4 teaspoonfuls | | |
| years of age. | (20 mL) in 24 hours. | | |
| children under 6 years | consult a doctor. | | |
| of age: | consult a doctor. | | |
| Other information | this packaging is child-resistant. | | |
| | ure 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? Call 1-888-535-0305 9a.m 5p.m. CST | | | |
| | | | |
| | | | |

VANACOF

chlophedianol hydrochloride, dexchlorpheniramine maleate, and pseudoephedrine hydrochloride liquid

| Product Information | | | | | | | |
|---------------------------------------------------------------------|-----------------------------------|--------------------|---------------------------------|---------------|--------------------|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | | NDC:58809-999 | | | |
| Route of Administration | ORAL | | | | | | |
| | | | | | | | |
| Active Ingredient/Active | | | | | | | |
| Active ingredient/Active | Molety | | | | | | |
| Ingred | lient Name | | Basis of Stre | ength | Strength | | |
| CHLOPHEDIANOL HYDROCHLOR - UNII:42C50P12AP) | I DE (UNII: 69QQ58998Y) (C | HLOPHEDIANOL | CHLOPHEDIANOL HYDROCHLORIDE | | 12.5 mg in 5 mL | | |
| DEXCHLORPHENIRAMINE MALEA (DEXCHLORPHENIRAMINE - UNII:3Q9 | | | DEXCHLORPHENIR MALEATE | AMINE | 1 mg in 5 mL | | |
| PSEUDOEPHEDRINE HYDROCHLO (PSEUDOEPHEDRINE - UNII:7CUC9DI | | | PSEUDOEPHEDRIN HYDROCHLORIDE | IE | 30 mg in 5 mL | | |

| | edients | | | | |
|-------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------|----------------------|--|
| Ingredient Name | | | Strength | | |
| SODIUM BENZOA | TE (UNII: OJ | 245FE5EU) | | | |
| ANHYDROUS CITR | RIC ACID (L | INII: XF417D3PSL) | | | |
| GLYCERIN (UNII: PI | DC6A3C00> | () | | | |
| PROPYLENE GLYC | OL (UNII: 6 | DC9Q167V3) | | | |
| SORBITOL (UNII: 5 | 06T60A25R |) | | | |
| WATER (UNII: 0590 | QF0KO0R) | | | | |
| SODIUM CITRATE | (UNII: 1Q73 | 3Q2JULR) | | | |
| SUCRALOSE (UNII: | 96K6UQ3Z | D4) | | | |
| | | | | | |
| | | | | | |
| Product Char | acterist | ics | | | |
| Color | | | Score | | |
| Shape | | | Size | | |
| Flavor | | TUTTI FRUTTI | Imprint Code | | |
| Contains | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Packaging | | | | | |
| | | Package Description | Marketing Start Date | Marketing Er Date | |
| # Item Code | 12 in 1 TR | - · | - | - | |
| # Item Code 1 NDC:58809-999- 02 | IZINIIR | - · | Date 04/22/2008 | - | |
| # Item Code 1 NDC:58809-999- 02 1 NDC 50000 000 | 12 in 1 in 1 15 mL in 1 Product | AY | Date 04/22/2008 | - | |
| NDC:58809-999- 02 NDC:58809-999- | 15 mL in 1 Product 473 mL in | AY L BOTTLE; Type 0: Not a Combination | Date 04/22/2008 | - | |
| # Item Code 1 NDC:58809-999- 02 1 2 NDC:58809-999- | 12 IN 1 TR 15 mL in 1 Product 473 mL in Product | AY L BOTTLE; Type 0: Not a Combination 1 BOTTLE; Type 0: Not a Combinatio | Date 04/22/2008 | - | |

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|---------------------------------------------|-------------------------|-----------------------|
| OTC Monograph Drug | M012 | 04/22/2008 | |
| | | | |

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 5/2024

GM Pharmaceuticals, INC