VANACOF DM- dextromethorphan hydrobromide, guaifenesin, and phenylephrine 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 DM

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NDC 58809-555-08

8 fl. Oz. (240 mL)

Active ingredients(in each 15 mL (TBSP))

Dextromethorphan HBr 18 mg

Guaifenesin 200 mg

Phenylephrine HCl 10 mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep
  - nasal congestion due to a cold

Warnings

Do not use

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema
- a cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland

When using this product

do not use more than directed

Stop use and ask a doctor if:

- nervousness, dizziness or sleeplessness occurs
- symptoms do not improve within 7 days or are accompanied by a fever, rash or persistent headache. A persistant 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 6 doses in any 24-hour period
- use enclosed dosage cup or tablespoon (TBSP)
- dose as follows or as directed by a doctor

Adults and children 12 years of age and over:	15 mL (1 TBSP) every 4 hours, not to exceed 90 mL (6 TBSP) in a 24 hour period.
Children 6 to under 12 years of age:	7.5 mL (1/2 TBSP) every 4 hours, not to exceed 45 mL (3 TBSP) in a 24 hour period.
Children under 6 years of age:	Consult a doctor.

Other information

- Each 15 mL (TBSP) contains: **Sodium 8 mg.**
- store at 68-86°F (20-30°C).

Inactive ingredients

citric acid anhydrous, glycerin, masking agent, propylene glycol, purified water, raspberry flavor, sodium benzoate, sodium citrate dihydrate, sodium saccharin, sorbitol

Questions or Comments?

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

Distributed by:

GM Pharmaceuticals, Inc.

Fort Worth, TX 76118

KEEP LEAFLET AFTER OPENING

Rev. 02/23

PRINCIPAL DISPLAY PANEL

NDC 58809-555-08

VANACOF DM

Cough

Cold/Congestion

Raspberry Flavor

8 fl. oz. (240 mL)

Drug Facts

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- a cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland

When using this product do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days 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.

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Other information

- each 15 mL (1 TBSP) contains: **Sodium 8 mg**
- read all product information before using
- store at 20° to 30°C (68° to 86°F)

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Drug Facts (continued)

Inactive ingredients

citric acid anhydrous, glycerin, masking agent, propylene glycol, purified water, raspberry flavor, sodium benzoate, sodium citrate dihydrate, sodium saccharin, sorbitol

Questions or comments?

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VANACOF DM

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58809-555
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	18 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:58809-555-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/01/2013	

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 8/2023 GM Pharmaceuticals, INC