VANACOF XP COUGH / CHEST CONGESTION- dextromethorphan hbr, guaifenesin solution GM Pharmaceuticals, INC

VANACOF XP Cough / Chest Congestion

Active Ingredients (in each 15 mL (1TBSP))

Dextromethorphan HBr 18 mg Guaifenesin 396 mg

Purpose

Cough Suppressant

Expectorant

Uses

- lelps 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

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 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, chronic bronchitis, or emphysema
- ■ a cough that occurs with too much phlegm (mucus)

When using this product

do not use more than directed

Stop use and ask a doctor if

■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

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
- dose as follows or as directed by a doctor mL= milliliter

| adults and children 12 years of age and over: | 15 mL (1 TBSP) every 4 hours, not to exceed 90 mL (6 TBSP) per 24 hours |
|---|--|
| | 7.5 mL (1/2 TBSP) every 4 hours, not to exceed 45 mL (3 TBSP) per 24 hours |
| children under 6 years: | consult a doctor. |

Other information

■ each 15 mL (1 TBSP) contains: Sodium 6 mg

■ store at 20° to 30°C (68° to 86°F)

Inactive ingredients

citric acid, flavors, glycerin, l-menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?

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

Tamper evident by foil seal under cap. Do no use if foil seal is broken or missing.

Distributed by: GM Pharmaceuticals, Inc. Fort Worth, TX 76118

NDC 58809-187-08

VANACOF® XP

COUGH / CHEST CONGESTION

Each 15 mL (1 TBSP) contains:

Dextromethorphan HBr.....18 mg

Guaifenesin396 mg

Raspberry-Mint Flavor

Alcohol Free / Sugar Free / Gluten Free / Dye Free



8 fl oz (237 mL)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Drug Facts

Active ingredients (in each 15 mL (1TBSP))

PurposeExpectorant

Dextromethorphan HBr 18 mg. Guaifenesin 396 mg.....

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

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 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

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a cough that occurs with too much phlegm (mucus) When using this product do not use more than directed

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Drug Facts (continued)

Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious

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

| dose as follows or as di | rected by a doctor mL= milliliter |
|---|--|
| adults and children 12 years of age and over: | 15 mL (1 TBSP) every 4 hours, not to exceed 90 mL (6 TBSP) per 24 hours |
| children 6 to under 12 years of age: | 7.5 mL (1/2 TBSP) every 4 hours, not to exceed 45 mL (3 TBSP) per 24 hours |
| children under 6 years: | consult a doctor. |

Other information

■ each 15 mL (1 TBSP) contains: Sodium 6 mg ■ store at 20° to 30°C (68° to 86°F)

Inactive ingredients citric acid, flavors, glycerin, I-menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

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



VANACOF XP COUGH / CHEST CONGESTION

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58809-187

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength 396 mg GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) **GUAIFENES IN** in 15 mL **DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) DEXTROMETHORPHAN** 18 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** in 15 mL

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | | |
| MENTHOL (UNII: L7T10EIP3A) | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | |

| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
|-------------------------------------|--|
| WATER (LINII: 0590E0KOOR) | |

| Product Characteristics | | | |
|-------------------------|-----------------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | RASPBERRY, MINT | Imprint Code | |
| Contains | | | |

| ı | Packaging | | | | |
|---|-----------|----------------------|---|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:58809-187- 08 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/06/2023 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 12/06/2023 | |
| | | | |

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 1/2024 GM Pharmaceuticals, INC