

PULMOVAC- guaifenesin, dextromethorphan hbr liquid
Menper Distributors, 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.

Active Ingredients (in each 5 mL tsp)

Guaifenesin 100 mg.....Expectorant
Dextromethorphan HBR 10 mg.....Cough suppressant

Expectorant
Cough Suppressant

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold and helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings Do not exceed recommended dosage.

A persistent cough may be a sign of a serious condition. If cough persists more than one week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

Do not use:

- this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor.
- 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.

Keep out of reach of children

If you are pregnant or breast-feeding, ask a health professional before use. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not exceed 6 doses in 24 hours.

Adults and children over 12 years.....2 teaspoonfuls (10 mL) every 4 hours
Children 6 to under 12 years of age.....1 teaspoonful (5 mL) every 4 hours
Children 2 to under 6 years of age.....1/2 teaspoonful (2.5 mL) every 4 hours
Children under 2 years of age.....consult your physician

Other Information

- store this product between (15°-30°C) (59°-86°F)

Inactive Ingredients

citric acid, FD&C red #33, glycerin, methylparaben, propylene glycol, propylparaben, raspberry flavor, sucrose, water

PULMOVAC
COUGH SUPPRESSANT-EXPECTORANT

New Raspberry Flavor

For the temporary relief of cough due to the common cold

6 Fl. Oz. (178 mL)

Drug Facts

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Directions

Do not exceed 6 doses in 24 hours.

age	dose
Adults and children 12 years of age and over	2 teaspoonsful (10 mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4 hours
Children 2 to under 6 years of age	½ teaspoonful (2.5 mL) every 4 hours
Children under 2 years of age	consult your doctor

Other Information

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Inactive Ingredients citric acid, D&C red #33, glycerin, methylparaben, propylene glycol, propylparaben, raspberry flavor, sucrose, water

TAMPER-EVIDENT: DO NOT USE THIS PRODUCT IF SEAL ON BOTTLE IS TORN, BROKEN OR MISSING

Distributed by: **Menper Distributors, Inc.**
6500 N.W. 35th Ave., Miami, FL 33147

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PULMOVAC

guaifenesin, dextromethorphan hbr liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-031
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
RASPBERRY (UNII: 4N14V5R27W)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-031-06	1 in 1 CARTON		
1		180 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/21/2012	

Labeler - Menper Distributors, Inc. (101947166)

Revised: 8/2013

Menper Distributors, Inc.