# PULMOVAC- guaifenes in, 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.

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## Active Ingredients (in each 5 mL tsp)

Guaifenesin 100 mg......Expectorant

Dextromethorphan HBR 10 mg.....Cough suppressant

Expectorant

Cough Suppresant

#### 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.

## **IKeep 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**

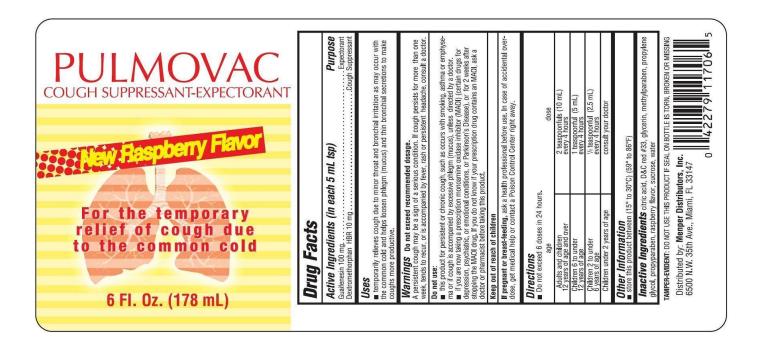
• Do not exceed 6 doses in 24 hours.

#### **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**

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	
<b>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (UNII: 9 D2RTI9 KYH) (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: Z8 IX2SC1OH)	
RASPBERRY (UNII: 4N14V5R27W)	
SUCROSE (UNII: C151H8 M554)	
WATER (UNII: 059QF0KO0R)	

P	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.