

BRONKISAN- 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 5mL tsp)

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

Expectorant
Cough Suppressant

Uses

- temporarily relieves cough due to minor throat and bronchial irritations 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 reoccur, 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.

age	dose
Adults and children 12 years of age and over.....	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 1/2 teaspoonful (2.5 mL)

6 years of age..... every 4 hours

Children under 2 years of age..... consult your doctor

Other information

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

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

Bronkisan

■ Cough Suppressant

■ Expectorant

For the Temporary Relief of
Cough Due To The Common Cold

Distributed By:
Menper Distributors
6500 N.W. 35th Avenue
Miami, FL 33147

(178 mL) 6 Fl.Oz.

Drug Facts

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Drug Facts (continued)

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Inactive Ingredients Artificial raspberry flavor, citric acid, D&C red color #33, methylparaben, propylene glycol, propylparaben, purified water, sucrose.

TAMPER EVIDENT: Do not use if seal on bottle is torn, broken or missing.

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BRONKISAN			
guaifenesin, dextromethorphan hbr liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-032
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

RASPBERRY (UNII: 4N14V5R27W)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-032-06	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.