# BREACOLD CHILDREN- 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.

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# Active ingredients (in each 15mL tsp)

Guaifenesin 100 mg......Expectorant

Dextromethorphan HBr 10 mg......Cough suppressant

# purpose

Expectorant

Cough Suppressant

## Uses

Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the commun cold and help loosen phleg, (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 for 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 asthma, 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

Children 6 to under 1 teaspoonful (5 mL)

12 years of age..... 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**

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

# **Questions?**

Call 1-800-560-5223 M-F 9 AM to 4 PM Eastern.

· La Tos · La Congestión de Pecho/Mucosa



Sabor a Frambuesa

DEXTROMETORFAN HBR (Supresor de la Tos)

**GUAIFENESINA** (Expectorante)

Contenido: 4 Fl. Oz (120 mL)

## Factores Farmacológicos

Ingredientes activos (en cada 15 mL) Propósito

temporal de la tos debido a irritación de la garganta y bronqui ada al resfriado común o gripe y ayuda a aflojar la flema (muci eciones bronquiales para hacer la tos más productiva.

- Justa
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  tiene asma, o si la tos se acompañada por flerna excesiva
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  si sisted está formando ahora alguna medicina taba prescripción
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Instrucciones ■ No exceda más de 6 dosis en 24 horas.			
edad dosis			
Niños de 6 a menores de	1 cucharada (15 mL)		
12 años de edad	cada 4 horas		
Niños de 2 a menores de	1/2 cucharada (7.5 mL)		
6 años de edad	cada 4 horas		

Ingredientes inactivos ácido cítrico, D&C rojo #33, glic metilparabeno, propilenglicol, propilparabeno, sabor a frambuesa sucrosa, agua

## Preguntas? Ilama 1-800-560-5223 L-V 9 AM a 4 PM Est

EVIDENCIA DE SEGURIDAD: NO USAR ESTE PRODUCTO SI EL SELLO IMPRESO SOBRE LA TAPA DE LA BOTELLA ESTA TORCIDO, ROTO O FALTA.

# Distributed by/Distribuído por: **Menper Distributors, Inc.** 11421 N.W. 107 Street, Suite 24, Miami, FL 33178 www.menperdistributors.com

· Cough · Chest Congestion/Mucus



Raspberry Flavor

DEXTROMETHORPHAN HBR (Cough Suppressant)

> **GUAIFENESIN** (Expectorant)

Contents: 4 Fl. Oz (120 mL)

Active ingredients (in each 15 mL)
Dextromethorphan HBr 10 mg......Col
Guaifenesin 100 mg Purposes

Directions ■ Do not exceed 6 doses in 24 hours, age dose		
Children 6 to under	1 tablespoonful (15 mL)	
12 years of age	every 4 hours	
Children 2 to under	1/2 tablespoonful (7.5 mL)	Ī
6 years of age	every 4 hours	
Children under 2 years of age	consult your doctor	ī

Other information
■ store this product between 15° to 30°C (59° to 86°F)

Inactive ingredients citric acid, D&C red #33, glycerin, methylparaben, propylene glycol, propylparaben, raspberry flavo

## Questions? call 1-800-560-5223 M-F 9 AM to 4 PM Ea

TAMPER-EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED CELLO-B OVER CAP IS TORN, BROKEN OR MISSING.



## **BREACOLD CHILDREN**

guaifenesin, dextromethorphan hbr liquid

## **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-007
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**ORAL Route of Administration** 

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL

## **Inactive Ingredients**

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Ina	redi	ent	Na	me

CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
RASPBERRY (UNII: 4N14V5R27W)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53145-007- 04	1 in 1 CARTON	02/21/2012		
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product			

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: 2/2022 Menper Distributors, Inc.