

BREACOLD ADULT- 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 10mL tsp)

Guaifenesin 200 mg.....Expectorant
Dextromethorphan HBr 20 mg.....Cough suppressant

Purpose

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.

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 smoking, asthma, chronic bronchitis, or emphysema, or where 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 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 under 12 years of age	Do not use

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

Raspberry
Adult
FLAVOR
GUAIFENESIN, DEXTROMETHORPHAN HBr
BREA-COLD

BREA-COLD

GUAIFENESINA, DEXTROMETORFAN HBr

Adulto
Jarabe Sabor
Frambuesa

**ALIVIA LA TOS
EXPECTORANTE**

Para alivio temporal
de la tos causada por el
resfriado común a la gripe

Contenido: 4 Oz FL (120 mL)

Factores Farmacológicos

Ingredientes activos (en cada 10 mL) Propósitos
Dextrometorfan HBr 20 mg..... Alivio de la Tos
Guaifenesina 200 mg.....Expectorante

Usos

■ Alivio temporal de la tos debido a irritación de la garganta y bronquios, asociada al resfriado común o gripe y ayuda a aliviar la flema (muco) y secreciones bronquiales para hacer la tos más productiva.

Advertencias

No exceder la dosis recomendada. Una tos persistente puede ser señal de una condición seria. Si la tos perdura por más de una semana, regresa o está acompañada por fiebre, dolor de cabeza o erupciones en la piel, consulte a su médico.

No usar

■ este producto para tos persistente o crónica, tal como ocurre si fuma, tiene asma, bronquitis crónica o enfisema o si la tos es acompañada por flema excesiva (secreción), sólo por indicación médica.
■ si usted está tomando ahora alguna medicina bajo prescripción que contenga inhibidores de la monoaminooxidasa (MAOI) (ciertas drogas para la depresión, síquicas, o condiciones emocionales, o enfermedad de Parkinson) o pasadas 2 semanas después de haber ingerido medicamentos que contengan MAOI. Si usted no está seguro que el medicamento que usted está tomando contiene MAOI, consulte a su doctor o a un farmacéutico antes de usarlo.

Mantener fuera del alcance de los niños.

Si está embarazada o lactando, pregunte a un profesional de la salud antes de usarlo. En caso de sobredosis accidental, busque ayuda médica o contacte a un Centro de Control de Envenenamiento inmediatamente.

Instrucciones ■ No exceda más de 6 dosis en 24 horas.

edad	dosis
Adultos y niños 12 años de edad o más	2 cucharaditas (10 mL) cada 4 horas
Niños menores de 12 años de edad	No use

Otra información

■ conserve este producto entre 15° a 30°C (59° a 86°F)

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

Preguntas? llame 1-800-560-5223 L-V 9 AM a 4 PM Este.

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

Distribuido por:
Menper Distributors, Inc.
11421 N.W. 107 Street Suite #24
Miami, FL 33178
www.menperdistributors.com

BREA-COLD

GUAIFENESIN, DEXTROMETHORPHAN HBr

Adult
Raspberry
Flavor

**COUGH SUPPRESSANT
EXPECTORANT**

For the temporary relief of cough
due to the common cold

Contents: 4 FL Oz (120 mL)

Drug Facts

Active ingredients (in each 10 mL) Purposes
Dextromethorphan HBr 20 mg.....Cough suppressant
Guaifenesin 200 mg.....Expectorant

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

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Do not use

■ this product for persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis 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.

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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 teaspoonsfuls (10 mL) every 4 hours
Children under 12 years of age	Do not use

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 flavor, sucrose, water

Questions? call 1-800-560-5223 M-F 9 AM to 4 PM Eastern.

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

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BREACOLD ADULT

guaifenesin, dextromethorphan hbr liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-040
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL

Inactive Ingredients

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

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-040-04	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)