## BRONCOMAR DM- dextromethorphan hbr, guaifenes in liquid Gadal Laboratories 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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## Acvtive ingredients: (in each 5ml) Purpose

Dextromethorphan HBr 10 mg ...... Cough Suppressant

Guaifenesin 100 mg ...... Expectorant

## **Purpose**

**Cough Suppressant** 

Expectorant

## Uses

- ¶Help loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.
- Teporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold

## Warnings

## Do not exceed recommended dosage

## Do not use

- If you are now taking a prescription monoamine oxidase inhibitor (MAOI)( certain drugs for depression, psychiatric conditions, or Parkinson's disease) or for 2 weeks after stopping the MAOI drug.
- if you do not know if your prescription drug contains on MAOI ask your doctor or pharmacist before taking this product
- if you have a chronic pulmonary disease or shortness of breath unless directed by a doctor
- avoid alcoholic beverages while you are taking this product

## **Ask** the doctor before use if you have

- Clough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

## Stop use and ask the doctor if

- ¶Nervoisness, dizziness or sleeplessness occurs.
- Cough persists for more than 1 week, tends to recur, or accompanied by fever, rash or persistent headache. A persistent cough may be sign of a serious condition

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## **Directions**

- Do not take more than 6 doses in any 24-hour period
- Shake well before use

**□Age Dose** 

□Adults and children 12 years and over 10 mL (2 tsps) every 4 hours Children 6 to under 12 years of age. 5 mL (1 tsps) every 4 hours

**Output** Children under 6 years of age **Do not use** 

## **Inactive ingredients**

Blue cohosh, citric acid, echinacea, eucalyptus oil, ginkgo biloba, gold seal root, honey, honey flavor, horehound herb, licorice root, menthol, mullein, myrrh, potassium sorbate, slippery elm bark, sodium benzoate, propylene glycol, water, sodium chloride, sucralose, wild cherry bark and zinc sulfate.



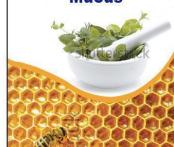


**Rroncomar** 

# **Broncomar**

**Expectorant** 

**Relieves Cough** Chest congestion Mucus



Dextromethorphan & Guaifenesin plus an exceptional Herbal Blend.

Alcohol Free

SYRUP

Net Wt. 6 fl. Oz. (177 ml)

Active ingredients: (in each 5ml).. Purpose Dextromethorphan HBr USP 10mg...... Guaifenesin USP 100mg...

- Help loosen phleam (mucus) and thin bronchial secretions to
- drain bronchial tubes and make cough more productive.

  Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold

## Warnings

o not exceed recommended dosage.

- In and use

  If you are now taking a prescription monoamine oxidase inhibitor
  (IMAOI)( certain drups for depression , psychiatric 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 your doctor or pharmacist before taking this product.

  If you have a chronic pulmonary disease or shortness of breath
  unless directed by a doctor.

  Avoid alcoholic beverages while you taking this product.

Ask the doctor before use if you have

Cough that occurs with too much phlegm (mucus)

Cough that last or is a chronic such as occurs with smoking ,
asthma, chronic bronchitis or emphysema.

Stop use and ask the doctor if

Nervousness, dizziness or sleeplessness occurs.

Cough persists for more than 1 week, tends to recur, or accompanied by fever, rash or persistent headache. A persistent cough may be sign serious condition

If pregnant or breast-teeding, ask a health professional before

use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Avoid alcoholic beverages while you taking this product.

## Directions:

■ Do not take more than 6 doses in any 24-hour period.
■ Shake well before use

Age	Dose
Adults and Children 12 years and over	10ml (2 tsps) every 4 hours
Children 6 to under 12 years of age.	5ml (1 tsps) every 4 hours
Children under 6 years of age	Do not use

### Other Information

- Each 5 ml contains: sodium 8 mg
   Store Between 15-30° C ( 59-86° F )
   Tamper Evident Feature Do not use if seal under cap is torn,
   broken or missing

Inactive Ingredients
Blue Cohosh, Citric Acid, Echinacea, Eucalyptus Oil, Ginkgo
Bluba, Golden Seal Root, Honey Pure, Honey flavor, Horehound
Harb, Licorice Root, Menthol, Mullein, Myrth, Potassium Sorbates
Stippery Elm Bark, Sodium Benzoate, Propylene Glycol, Purified
Water, Sodium Chloride, Sucralose, Wild Cherry bark and Zinc

Questions or Comments?

all Weekdays from 9:30 AM to 5 PM EST at Tel 305 2618762

Distributed by essential Oroducts Miami, FI, 33126 Made In U.S.A.

# **Broncomar®**

Expectorante

Alivia la Tos Congestión de Pecho & Mucosidad



Dextrometorfan & Guaifenesina Además de un Excepcional Compuesto Herbario.

LIBRE DE PARABENOS

Sin Alcohol

**JARABE** 

Peso Neto. 6 fl. Oz. (177 ml)

## Información General

Ingredientes Activos:(En cada 5 ml) . Propósito

- Ayuda a aflojar la flema(mucosidad) y las secreciones
  bronquiales para drenar los tubos bronquiales, haciendo la tos
  mas productiva
   Alivia temporalmente la tos debida a la irritación leve de la
- garganta o de los bronquios que suele ocurrir con un resfriado

- gargana o de dos dronquos que sue e ocurnir con un resinado 
  Advertencias

  Ne exceda la dosis recomendada.

  Ne use este producto

  Si usted esta tomando un inhibidor de monoaminooxidasa 
  ((IMAO) (por E). Algunos medicamentos para la depresión, 
  trastomos psiquiátricos o emocionales o para la entermedad de 
  Parkinson) espere 2 semansa después de suspender el IMAO 
  antes de comenzar a tomarlo.

  Si usted no sabe si su medicamento con receta medica contiene 
  este producto.

  Si tiene una entermedad crónica pulmonar o dificillad para 
  respirar a menos que lo indique su doctor.

  Predintale a su medico antes de usar este aroducto si usidel liene

- Pregúntele a su medico antes de usar este producto si usted tiene
- Tos con mucha flema o (mucosidad)

  Tos persistente o crónica, como ocurre en casos de personas que fuman y/o asma, bronquitis crónica o enfisema.

que fuman y/o asma, bronquitis crónica o enfisema.

Descontinhe el uso de este producto y consulte a su medico sí

Se produce nerviceismo, mareos o falta de sueño.

Se produce nerviceismo, mareos o falta de sueño.

acompañada de filéria este cemana, lendra e repetirse, o acompañada de filéria este dun o tos persistente, este puede ser un signo de enfermedad grave.

Si esta embarazada o en periodo de lactancia.

Consulte con un protesional de la salud antes de usar este producto.

Mantenga haver del alcance de los nilhos, en caso de sobredosis obtenga ayuda medica o póngase en contacto con un centro de envenenamiento immediatamente.

Evite las bebidas alcohólicas mientras tome este producto.

Instrucciones :
■ No tome mas de 6 dosis en un periodo de 24 horas.
■ Agitese antes de usar:

Adultos y niños mayores de 12 años 10ml (2 cucharaditas) cada 4 horas ños de 6 años hasta 12 años 5ml (1 cucharadita) cada 4 horas Niños menores de 6 años de edad No Utilice este producto

### Información adicional

cada 5 ml contiene : 8 mg de sodio conservar a una temperatura de entre 15-30° C (59-86°F) lo Acepte: si el sello de seguridad de la tapa esta roto a falta

## Ingredientes inactivos

rigredi entres inactivos supresente de Euralipio, Acido Citrico, Agua Purificada, Barbasco, oruro de Sodio, Cohosh Azul, Corteza de Cereza Silvestre, orteza de Silpepor Plim. Echinacae, Ginko Biloba, Marrubium ulgare, Mentol, Miel pura de Abeja, Mirra, Propilen Glicol, Raiz Pegaliz, Raiz de Sello De Oro, Sabor a Miel, Sodio Benzoato, orbato de Potasio, Sucralosa y Sulfato de Zino.

Preguntas o Comentarios? Llamar de 9:30 AM a 5 PM tiempo este, en días laborables TEL 305 32618762.

www.jjjdistributors.com



NDC 53113-217-06

## BRONCOMAR DM

dextromethorphan hbr, guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-217
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients	
Ingredient Name	Strength
CAULO PHYLLUM THALICTRO IDES ROOT (UNII: JTJ6 HH6 YEH)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
ECHINACEA, UNSPECIFIED (UNII: 4N9 P6 CC1DX)	
EUCALYPTUS CAMALDULENSIS LEAF OIL (UNII: SN6D1J15I6)	
GINKGO BILOBA WHOLE (UNII: 660486U6OI)	
GOLDENSEAL (UNII: ZW3Z11D0JV)	
HO NEY (UNII: Y9 H1V576 FH)	
HO REHO UND (UNII: K08036 XEJV)	
LICORICE (UNII: 61ZBX54883)	
MENTHOL (UNII: L7T10 EIP3A)	
MULLEIN LEAF (UNII: 9936O846LI)	
MYRRH (UNII: JC71GJ1F3L)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ULMUS RUBRA BARK (UNII: 91QY4PXU8Q)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PRUNUS SERO TINA BARK (UNII: 5D48E975HA)	
ZINC SULFATE (UNII: 89 DS0 H9 6 TB)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:53113-217-06	1 in 1 CARTON		
1	177 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/01/2014	

## Labeler - Gadal Laboratories Inc (841305639)

Revised: 6/2014 Gadal Laboratories Inc