BRONCOMAR MAXIMUM- 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.

Acvtive ingredients: (in 10 ml) Purpose

Dextromethorphan HBr 30 mg Cough Suppressant

Guaifenesin 200 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.

IKeep 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

□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

©Children under 6 years of age Do not use

Inactive ingredients

Aloe vera, citric acid, disodium EDTA, FD&C Red #40, glycerin, hydroxyethyl cellulose, natural strawberry flavor, water, sodium benzoate, sorbitol 70%, sucralose



Broncomar

Broncomar[®]

Maximum Cough Relief



Alcohol & Sugar Free PARABEN FREE

Helps Chest Congestion Loosens Mucus



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

Drug Facts

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Other Information

- Each 10 ml contains: sodium 2 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

Noe Vera , Citric Acid, Disodium EDTA, FD&C Red #40, Glycerin, Hydroxyethyl Cellulose, Natural Strawberry Flavor, Purified Wate Sodium Benzoate. Sorbitol 70% USP Sucralose .

Questions or Comments?

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

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

Broncomar°

Máximo Alivio de la Tos



LIBRE DE PARABENOS

Alivia la Congestión de Pecho

Afloja la Mucosidad





JARABE

Peso Neto 6 fl. Oz. (177 mL)

Información General

Ingredientes Activos: (en 10ml).. Propósito Dextrometorian HBr USP 30 mg. Guaifenesina USP 200 mg.......

Usos

- USOS

 Ayuda a aflojar la flema(mucosidad) y las secreciones
 bronquiales para drenar los tubos bronquiales, haciendo la to:
 mas productiva

 Alivia temporalmente la tos debida a la irritación leve de la
 garganta o de los bronquios que suele ocurrir con un resfriad

Advertencias

- *No use este producto* Si usted esta tomando un inhibidor de monoaminooxidasa (IMAO) (por Ej. Algunos medicamentos para la depresión, trastornos psiquiátricos o emocionales o para la enfermedad de Parkinson) espere 2 semanas después de suspender el IMAO antes de comenzar a tomarlo.
- Si usted no sabe si su medicamento con receta medica conti-I utilità di osane si su medicamento con receta medica contien un IMAO, consulte a su medica o farmacéutico antes de tomai este producto.
 Si tiene una enfermedad crónica pulmonar o dificultad para respirar a menos que lo indique su doctor.

 Evite las bebidas alcohólicas mientras tome este producto.

Pregúntel e a su medico antes de usar este producto si usted tie

- regularez a si necido antes se usar este producto si usiero del I Tos con mucha flema o (mucosidad) I 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.

Descontinúe el uso de aste producto y consulte a su medico si

Se produce nerviosismo, mareos o falta de sueño.

La tos persiste por más de 1 semana, liende a repetirse, o
acompañada de fiebre, erupción o los persistente, este puede ser
un signo de enfemendad grave
SI esta embarazada o en periodo de lactancla.
Consulte con un profesional de la salud antes de usar este product
Mantenga fuera del alcance de los nilhos, en caso de sobredosis
obtenga ayuda medica o póngase en contacto con un centro de
envenenamiento immediatamente.

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

Edad	Dosis
Adultos y niños mayores de 12 años	10ml (2 Ctas.) cada 6 horas
Niños de 6 hasta 12 años	5ml (1 Cdta.) cada 6 horas
Niños menores de 6 años de edad	No Utilice este producto

Información adicional

- Cada 10 ml contiene : 2 mg de sodio Conservar a una temperatura de entre 15-30° C (59-86°F) No Acepte: si el sello de seguridad de la tapa esta roto a fal

Ingredientes inactivos

Aleo Vera, Acido citrico, Agua Purificada, Benzonato Sodico,Colo Rojo FD&C # 40, EDTA Disodico, Glirecina, Hidroxietil Celulosa, Sabor Fresa Natural, Sorbitol 70% USP, Sucralosa.

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

www.jjjdistributors.com Made In U.S.A.



NDC 53113-216-06

BRONCOMAR MAXIMUM

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-216
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 10 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRO XYMETHYL CELLULO SE (UNII: 273FM27VK1)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:53113-216-06	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