

BRONCOMAR MAXIMUM COUGH RELIEF- dextromethorphan hbr, guaifenesin liquid
Danoso Corp./d.b.a. Essential Products

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.

Broncomar Maximum Cough Relief

Active Ingredients:(in each 10 ml.)	Purpose
Dextromethorphan Hydrobromide 30 mg	Cough Suppressant
Guaifenesin 200 mg.....	Expectorant

Uses:

- Helps loosen phlegm (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

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 MAOI drug.
- If you do not know if your prescription drug contains MAOI as 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 beverage while taking this product.

Stop use and ask a doctor

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

Ask 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.

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 exceed 6 doses in any 24 hour period.

AGE	DOSE
Adults and Children 12 years and over	10 ml (2 tsps) every 6 hours
Children 6 to under 12 years of age	5 ml (1 tsp) every 6 hours
Children under 6 years of age	Do not use

Other Information:

- Each 10 mls contains: sodium 4 mg
- Store between 15 - 30 degrees Celsius (59 - 86 Fahrenheit).
- Tamper Evident Feature: Do not use if seal under cap is torn, broken or missing.

Inactive Ingredient

Aloe Vera, Citric Acid, Disodium EDTA, FDC Red #40, Glycerin, Hydroxyethyl Cellulose, Natural Strawberry Flavor, Purified Water, Sodium Benzoate, Sorbitol 70% USP, Sucralose.

Questions or Comments

Call Weekdays from 9:30 AM to 5PM EST at Tel 305-261-762

Distributed by

Essential Products Miami FL 33126

www.jjjdistributors.com

Made in U.S.A.

Drug Facts

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Broncomar[®]

Maximum Cough Relief

Great Strawberry Flavor



Alcohol & Sugar Free
PARABEN FREE

Cough Suppressant
Expectorant

Helps Chest Congestion
&
Loosens Mucus

 

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

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.

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www.jjjdistributors.com
Made in U.S.A. Rev 02/14

Lot #.
Exp.Date.

BRONCOMAR MAXIMUN COUGH RELIEF

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70 242-103

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (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 LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70242-103-06	1 in 1 CARTON	01/01/2015	
1		177 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	10/01/2001	

Labeler - Danoso Corp./d.b.a. Essential Products (059741071)

Registrant - Danoso Corp./d.b.a. Essential Products (059741071)

Establishment

Name	Address	ID/FEI	Business Operations
All Pharma LLC		078572520	MANUFACTURE(70242-103)

Revised: 1/2016

Danoso Corp./d.b.a. Essential Products