BIOCOTRON- dextromethorphan, guaifenes in liquid Advanced Generic Corporation

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.

Drug Facts

Active Ingredients: (in each 5 mL tsp.) Purpose

Dextromethorphan Hydrobromide 10 mg...... Cough Suppressant

Guaifenesin 100 mg Expectorant

Purpose

©Cough suppressant

Expectorant

Ask a doctor before use if you have

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

When using this product, do not exceed recommended dosage

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

Do not Use

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 you are taking a prescription drug that contains an MAOI;ask your doctor or pharmacist before taking this product.

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, unless directed by a physician.

Age	Dose
adults and children 12 years and over	2 teaspoonfuls (10 mL) every 4 hours
children 6 years to under 12 years	1 teaspoonful (5 mL) every 4 hours
children under 6 years	ask a doctor

Uses

- temporarily relieves cough due to minor throat and bronchial irritations as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Inactive ingredients Icitric acid, cherry flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate and sucralose

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, FL 33166.

www.advancedgeneric.com

Drug Facts	
Active ingredients (in each 5 mL teaspoonful) Dextromethorphan HBR, USP	PurposeCough SuppressantExpectorant
Uses - temporarily relieves cough due to min irritations as may occur with a cold - helps loos thin bronchial secretions to make coughs more	en phlegm (mucus) and

Warnings - Do not use - 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 you are taking a prescription drug that contains a MAOI; ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have • cough that occurs with too much phlegm (mucus) • cough that lasts or is 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.

When using this product, do not exceed recommended dosage

Stop use and ask a doctor if • cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

Broncotron® is a registered trademark of Seyer Pharmatec.lophen® is a registered trademark of Qualitest Pharmaceuticals. This product is not manufactured, distributed or marketed by Seyer Pharmatec or Qualitest Pharmaceuticals.

Lot #:

Exp. Date:

NDC 45737-209-16

BIOCOTRON

- Cough Suppressant
- Expectorant

Alcohol FREE • Sugar FREE • Dye FREE

Cherry Flavor

Contains the same active ingredients as lophen® DM-NR & Broncotron®+

Manufactured For

advanced generic corporation Miami, FL 33147 www.advancedgeneric.com

16 fl. oz. (473 mL)

Drug Facts (continued)

Directions Do not take more than 6 doses in any 24-hour period, unless directed by a physician.

ı	age	dose	
ı	adults and children 12 years and over	2 teaspoonfuls (10 mL) every 4 hours	
ı	children 6 years to under 12 years	1 teaspoonful (5mL) every 4 hours	
	children under 6 years	ask a doctor	

Other information - store at room temperature 20°-25° C (68°-77° F). Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering.

PHARMACIST: Preserve and dispense in tight light resistant container with a child resistant cap as defined in the USP.

Inactive ingredients Citric acid, Cherry flavor, Methylparaben, Propylene glycol, Propylparaben, Purified water, Sodium citrate and Sucralose.

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, FL 33147. www.advancedgeneric.com

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING Code #: L-83
Rev. 12/17



BIOCOTRON

dextromethorphan, guaifenesin liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:45737-209

Route of Administration ORAL

Active Ingredient/Active Moiety

reduce ingredients reduced			
Ingredient Name	Basis of Strength	Strength	
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextro metho rphan Hydro bro mide	10 mg in 5 mL	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL	

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968 PHW8 QP)	
Water (UNII: 059QF0KO0R)	
Methylparaben (UNII: A218 C7H19 T)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY (Cherry Flavor)	Imprint Code	
Contains			

ı	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:45737-209-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 0 9	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 1/0 1/20 0 9	

Labeler - Advanced Generic Corporation (831762971)

Revised: 12/2020 Advanced Generic Corporation