BIOCOTRON-D- dextromethorphan hbr, guaifenesin, phenylephrine hcl suspension/drops 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 5mL)	Purpose
Dextromethorphan HBr, 10 mg	Cough Suppressant
Guaifenesin, 200 mg	Expectorant
Phenylephrine HCl, 5 mg	Nasal Decongestant

Uses

Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes. Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold. Temporarily relieves nasal congestion due to the common cold.

Warnings:

Ask a doctor before use if you have:

Heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to an enlarged prostate gland, cough that last or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Ask doctor or pharmacist before use if you are taking any other nasal decongestant or stimulant.

When using this product do not use more than directed.

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

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 a doctor or pharmacist before taking this product.

Stop use and ask a doctor before use if:

- you get nervous, dizzy or sleepless; symptoms do not get better within 7 or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

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

Directions: Do not take more than 3 doses in any 24-hour period.

Age	Dose
Adults and children 12 years of age and over	2 teaspoons every 4 hours
Children 6 to under 12 years of age	1 teaspoon every 4 hours
Children 2 to under 6 years of age	1/2 teaspoon every 4 hours
Children under 2 years of age	Ask a doctor

Inactive ingredients: Carboxymethyl cellulose sodium, Cellulose, Citric Acid, Flavor, Propylene Glycol, Sodium Benzoate, Sodium Saccharin, Water

Questions or comments? 1-305-403-3788

Other information:Store at room temperature 15-30 degrees C (59-86 degrees F)

Tamper evident:Do not use if seal under cap (or cello-band over cap) is torn, broken or missing.

Each teas poonful (5mL) contains: Sodium 6 mg



BIOCOTRON-D

dextromethorphan hbr, guaifenesin, phenylephrine hcl suspension/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-208
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL	
OMET M253 / MOMA)	HYDKOCHLORIDE	III 5 ML	

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
WATER (UNII: 059QF0KO0R)		

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 NI	DC:45737-208-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 3/0 1/20 13	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	0 3/0 1/20 13	

Labeler - Advanced Generic Corporation (831762971)

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