BIOCOTRON PED- dextromethorphan hbr, guaifenesin, phenylephrine hcl 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 5mL) **Purpose**

Dextromethorphan HBr, 15 mg ..... Cough Suppressant

Guaifenesin, 350 mg ..... Expectorant

Phenylephrine HCl, 10 mg ..... Nasal Decongestant

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses

- non-narcotic cough suppressant which temporarily calms cough due to minor throat and bronchial irritation as may occur with the common cold
- calms the cough control center and relieves coughing
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive.
- temporarily relieves nasal congestion due to the common cold
- helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

Warnings:

Do no exceed recommended dosage

a persistent cough may be a sign of a serious condition. If cough persist for more than 1 week, tends to recur, or is accompanied by fever, rash or a persistent headache, constult a doctor

Do not use this product if you

are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional condition. or for two weeks after stopping the MAOI drug. If you do not know if your prescription drug contains a MAOI, ask a doctor or phamacist before taking thie product.

Ask doctor or pharmacist before use if you have

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.
- high blood pressure
- heart disease
- thyroid disease
- diabetes
- difficulty in urincation due to enlargment of the prostate gland

Stop use and ask a doctor if:

- nervousness, dizziness, or sleeplessness occur.
- if symptoms do not improve within 7 days or are accompanied by fever

Ask a doctor before use if you are taking sedatives or tranquilizers.

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

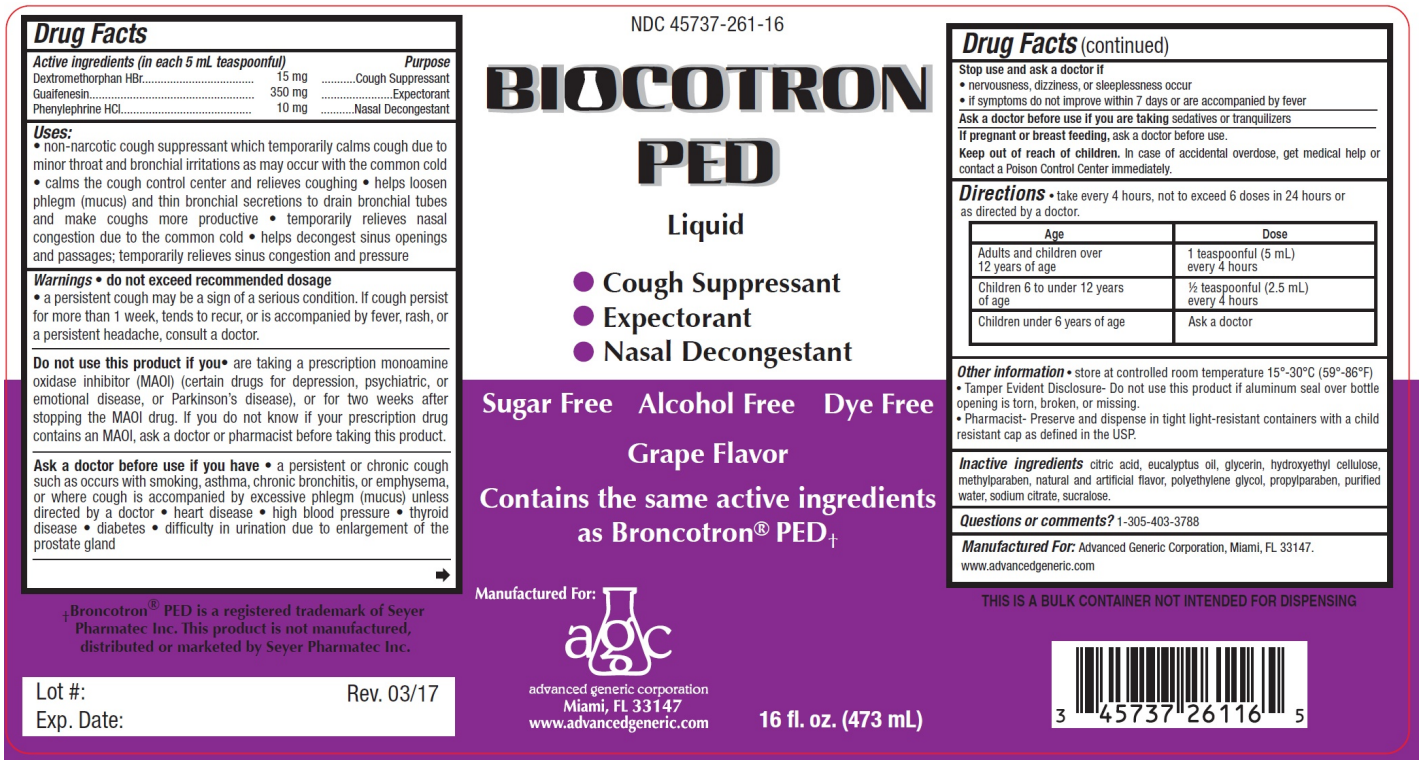
If pregnant or breast-feeding, ask a doctor before use.

Directions: Take very 4 hours, not to exceed 6 doses in 24 hours or as directed by physician

Age	Dose
Adults and children 12 years of age or older	1 teaspoonful (5 mL) every 4 hours
Children 6 to under 12 years of age	1/2 teaspoonful (2.5 mL) every 4 hours
Children under 6 years of age	Ask a doctor

Inactive ingredients: citric acid, eucalyptus oil, glycerin, hydroxyethyl cellulose, methylparaben, natural and artificial flavor, polyethylene glycol, propylparaben, purified water, sodium citrate, sucralose.

Questions or comments? 1-305-403-3788



BIOCOTRON PED

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45737-261
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	350 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-261-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2015	

Labeler - Advanced Generic Corporation (831762971)

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