BIODESP DM NF- 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, 10 mg ..... Cough Suppressant

Guaifenesin, 100 mg ..... Expectorant

Phenylephrine HCl, 5 mg ..... Nasal Decongestant

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses

- temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis), or other upper respiratory allergies:
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passages

Warnings:

Do no exceed recommended dosage

- A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur or is accompanied by a fever, rash or a persistent headache, consult 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 a doctor 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 unless directed by a doctor

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 immediately.

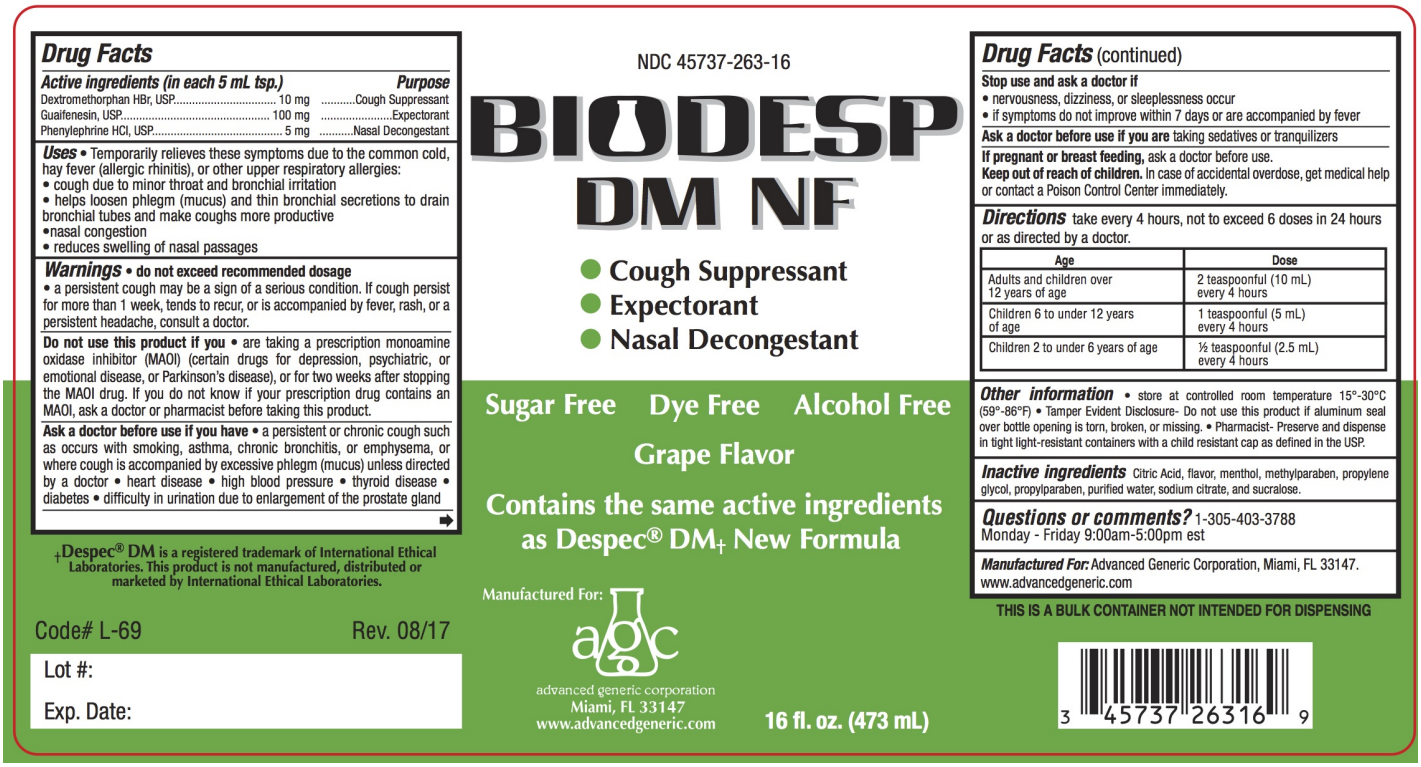
If pregnant or breast-feeding, ask a doctor before use

Directions: take every 4 hours, not to exceed 6 doses in 24 hours or as directed by a doctor.

Age	Dose
Adults and children 12 years of age and over	2 teaspoonfuls (10 mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4 hours
Children under 6 years of age	1/2 teaspoonful (2.5 mL) every 4 hours to consult a doctor

Inactive ingredients: citric acid, flavor, menthol, methylparaben, propylene glycol, propylparaben, pruified water, sodium citrate, and sucralose.

Questions or comments? 1-305-403-3788



BIODESP DM NF

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45737-263
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	100 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-263-16	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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