

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 pharmacist before taking this 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 urination due to enlargement 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, purified water, sodium citrate, and sucralose.

Questions or comments? 1-305-403-3788

Drug Facts

Active ingredients (in each 5 mL tsp.)

Dextromethorphan HBr, USP..... 10 mg	Cough Suppressant
Guaifenesin, USP..... 100 mg	Expectorant
Phenylephrine HCl, USP..... 5 mg	Nasal Decongestant

Purpose

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 not 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, consult a doctor.

Do not use this product if you

- are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional disease, or Parkinson's disease), or for two weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

NDC 45737-263-16

BIODESP

DM NF


- Cough Suppressant
- Expectorant
- Nasal Decongestant

Sugar Free Dye Free Alcohol Free

Grape Flavor

Contains the same active ingredients as Despec® DM+ New Formula

Manufactured For:



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

16 fl. oz. (473 mL)

Drug Facts (continued)

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

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

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

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

Age	Dose
Adults and children over 12 years of age	2 teaspoonful (10 mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4 hours
Children 2 to under 6 years of age	½ teaspoonful (2.5 mL) every 4 hours


Other information • store at controlled room temperature 15°-30°C (59°-86°F) • Tamper Evident Disclosure- Do not use this product if aluminum seal over bottle opening is torn, broken, or missing. • Pharmacist- Preserve and dispense in tight light-resistant containers with a child resistant cap as defined in the USP.

Inactive ingredients Citric Acid, flavor, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

Questions or comments? 1-305-403-3788
Monday - Friday 9:00am-5:00pm est

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

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING



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Code# L-69 Rev. 08/17

Lot #:

Exp. Date:

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: L7T10EP3A)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
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)

Revised: 1/2018

Advanced Generic Corporation