**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.*

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**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.

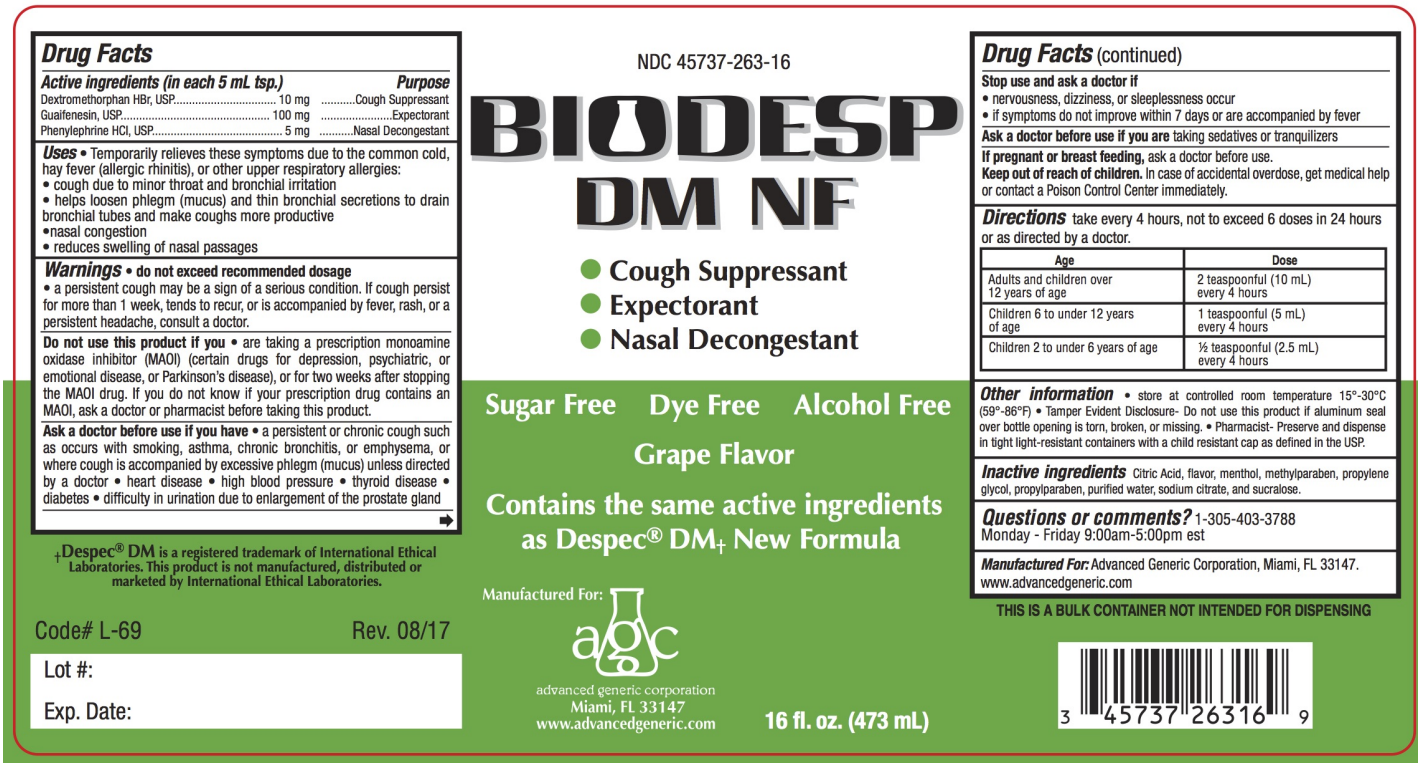
**If pregnant or breast-feeding,** ask a doctor before use

**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)

Revised: 12/2020 Advanced Generic Corporation