

**COUGH DM- dextromethorphan polistirex suspension  
ATLANTIC BIOLOGICALS CORP.**

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**DEXTROMETHORPHAN  
Major Pharmaceuticals Cough DM Drug Facts**

**Active ingredient (in each 5 mL)**

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide, USP

**Purpose**

Cough suppressant

**Uses**

temporarily relieves

- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the impulse to cough to help you get to sleep

**Warnings**

**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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Allergy Alert: Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

**Ask a doctor before use if you have**

- chronic cough that lasts as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)

**Stop use and ask a doctor if**

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- cough lasts more than 7 days, cough comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

## Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away 1-800-222-1222.

### Directions

- shake bottle well before use
- measure only with dosing cup provided. Do not use dosing cup with other products.
- dose as follows or as directed by doctor
- mL = milliliter

adults and children 12 years of age and over	10 mL every 12 hours, not to exceed 20 mL in 24 hours
children 6 to under 12 years of age	5 mL every 12 hours, not to exceed 10 mL in 24 hours
children 4 to under 6 years of age	2.5 mL every 12 hours, not to exceed 5 mL in 24 hours
children under 4 years of age	do not use

### Other information

- each 5 mL contains: sodium 5 mg
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided

### Inactive Ingredients

D&C Red #30 aluminum lake, D&C Yellow #10 aluminum lake, flavor, glycerin, high fructose corn syrup, methylparaben, polysorbate 80, polyvinyl acetate, povidone, propylparaben, purified water, sodium metabisulfite, sodium polystyrene sulfonate, sucrose, tartaric acid, tragacanth gum, triacetin, xanthan gum

### Questions or comments?

1-800-719-9260

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

### Package/Label Principal Display Panel

Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

12 HOUR COUGH RELIEF

Dosing Cup Included

Orange-Flavored Liquid

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions

COMPARE TO the Active Ingredient of DELSYM®

Alcohol-free

**DEXTROMETHORPHAN**

**POLISTIREX ER**

**ORAL SOLUTION**

**DELIVERS 60mg/10mL**

**ALCOHOL FREE ORANGE FLAVOR**

**EXP: XX/XX/XX LOT: XXXXXX**

**DIST. BY:**

**ATLANTIC BIOLOGICALS CORP.**



**17856631202**

**REV. 2**

**17856-6312-01**  
**DEXTROMETHORPHAN**  
**POLISTIREX ER ORAL**  
**SUSPENSION**  
**30 mg PER 5 mL**  
**DELIVERS 30mg/5mL**



See package insert for indications and dosage schedule

Alcohol Free Orange Flavored Cough Suppressant. Each 5 ml contains 5mg of Sodium. Store at 20° to 25°C (68° to 77°F).  
**\*\*Keep this and all medications out of the reach of children\*\***



**17856-6312-01 Dosage 30mg/5mL**  
**DEXTROMETHORPHAN :**  
**POLISTIREX ER ORAL Qty: 72 CUPS**  
**SUSPENSION**



GTIN: 00317856631211  
 S/N: XXXXXXXXXXXX  
 Exp: 11/12/24  
 Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.  
 Miami, FL 33179

Rev.08/21

**Call to Reorder:**

## COUGH DM

dextromethorphan polistirex suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-6312(NDC:0904-6312)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>POLISTIREX</b> (UNII: 5H9W9GTW27)
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>WATER</b> (UNII: 059QF0KOOR)
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)
<b>SODIUM POLYSTYRENE SULFONATE</b> (UNII: 1699G8679Z)
<b>SUCROSE</b> (UNII: C151H8M554)
<b>TARTARIC ACID</b> (UNII: W4888I119H)
<b>TRAGACANTH</b> (UNII: 2944357O2O)
<b>TRIACETIN</b> (UNII: XHX3C3X673)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)
<b>POLYVINYL ACETATE</b> (UNII: 32K497ZK2U)

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-6312-1	5 mL in 1 CUP; Type 0: Not a Combination Product	11/18/2024	
2	NDC:17856-6312-2	10 mL in 1 CUP; Type 0: Not a Combination Product	11/18/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091135	09/06/2012	

**Labeler -** ATLANTIC BIOLOGICALS CORP. (047437707)