COUGH DM- dextromethorphan polistirex suspension
ATLANTIC BIOLOGICALS CORP.

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

17856-6312-01
COUGH DM (DEXTROMETHORPHAN POLISTIREX) ER ORAL SUSPENSION (COUGH SUPPRESSANT)

UDOSE

See package insert for indications and dosage schedule

STORE AT 20° TO 25°C (68° TO 77°F). Each 5 ml contains: Sodium 5 mg.(Dextromethorphan polistirex equivalent to 30 mg dextromethorphan Hbr)
**** Keep this and all Medication out of the reach of children****

17856631201

17856-6312-01 **Dosage: 30MG / 5ML**

COUGH DM (DEXTROMETHORPHAN POLISTIREX) **Qty: 72 CUPS**

GTIN: 00117856631217
S/N: 01292001
Exp: 07/28/21
Lot: 012920

OTC

Packaged by:Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp,
Miami Fl 33179

Rev.09/19

Call to Reorder: 800.509.7592

COUGH DM

dextromethorphan polistirex suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-6312(NDC:0904-6312)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLISTIREX (UNII: 5H9W9GTW27)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
GLYCERIN (UNII: PDC6A3C0OX)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
SUCROSE (UNII: C151H8M554)	
TARTARIC ACID (UNII: W4888I119H)	
TRAGACANTH (UNII: 2944357O2O)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	

Product Characteristics

Color	ORANGE	**Score**	
Shape		**Size**	
Flavor	ORANGE	**Imprint Code**	
Contains			

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	01/29/2021	
2	NDC:17856-6312-2	10 mL in 1 CUP; Type 0: Not a Combination Product	06/16/2021	

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)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-6312) , repack(17856-6312)