

DELSYM- dextromethorphan suspension, extended release
ATLANTIC BIOLOGICALS CORP.

Delsym
12 Hour Cough Relief
Grape

Drug Facts

Active ingredient (in each 5 mL)

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide

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.

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 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.

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 a 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 7 mg**
- store at 20-25°C (68-77°F)
- dosing cup provided

Inactive ingredients

citric acid anhydrous, D&C red no. 33, edetate disodium, ethylcellulose, FD&C blue no. 1, flavor, high fructose corn syrup, methylparaben, partially hydrogenated vegetable oil (soybean, cottonseed), polyethylene glycol 3350, polysorbate 80, propylene glycol, propylparaben, purified water, sucrose, tragacanth, xanthan gum

Questions?

1-866-682-4639

You may also report side effects to this phone number.

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 16TH PLACE

MIAMI, FL 33179

**NDC 17856-0172-01Delsym® Dextromethorphan Polistirex
Extended-Release Suspension (Cough Suppressant) COUGH 12
HOUR
COUGH RELIEF® Grape
Flavored Liquid 10mL CUP 72 PER CASE Day or Night
SULFITE FREE
ALCOHOL FREE**

17856-0172-02

Delsym (Dextromethorphan
Polistirex)



ER- Suspension

30 MG/ 5 ML

Delivers 5 ML

See package insert for indications and dosage schedule

Store at 20-25°C (68-77°F) (COUGH
SUPPRESSANT)
***Keep this and all medication out of the reach
of children***



17856017202

17856-0172-02

Dosage 30 MG/ 5 ML

DELSYM

Qty: 72 CUPS

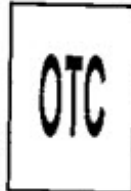


GTIN: 00117856017226

S/N: 01552301

Exp: 04/07/22

Lot: 015523



Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp,
Miami FL 33179

Rev.08/21

Call to Reorder: 300.509.7592

17856-0172-01
DELSYM
 (DEXTROMETHORPHAN
 POLISTIREX EQUIV TO
 DEXTROMETHORPHAN HBr)



See package insert for indications and dosage schedule



Store at 20°-25°C (68°-77°F)
 Cough Suppressant / Shake Well / Each 5 ml
 contains: sodium 7 mg
KEEP OUT OF THE REACH OF CHILDREN

17856-0172-01

Dosage: 60 MG/10 ML
ER-Oral Suspension

DELSYM

Qty: 72 Cups



GTIN: 00117856017219
 S/N: 01076801
 Exp: 12/25/20
 Lot: 010768

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

DELSYM

dextromethorphan suspension, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0172(NDC:63824-171)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan (UNII: 7355X3ROTS) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Polistirex (UNII: 5H9W9GTW27)	
anhydrous citric acid (UNII: XF417D3PSL)	
D&C Red NO. 33 (UNII: 9DBA0SBB0L)	
edetate disodium (UNII: 7FLD91C86K)	
ethylcellulose, unspecified (UNII: 7Z8S9VYZ4B)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
high fructose corn syrup (UNII: XY6UN3QB6S)	
methylparaben (UNII: A2I8C7HI9T)	
polyethylene glycol 3350 (UNII: G2M7P15E5P)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sucrose (UNII: C151H8M554)	
tragacanth (UNII: 2944357O2O)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0172-4	1 in 1 CUP, UNIT-DOSE	04/19/2024	
1	NDC:17856-0172-1	72 in 1 BOX, UNIT-DOSE		
1		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0172-3	1 in 1 CUP, UNIT-DOSE	04/19/2024	
2	NDC:17856-0172-2	72 in 1 BOX, UNIT-DOSE		
2		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018658	12/17/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0172)

Revised: 4/2024

ATLANTIC BIOLOGICALS CORP.