

DELSYM (DEXTROMETHORPHAN)- dextromethorphan suspension, extended release
Atlantic Biologicals Corps

Delsym (Dextromethorphan) Suspension Extended-Release®

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

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. **Do not use**

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)

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. **Stop use and ask a doctor if**

ask a health professional before use. **If pregnant or breast-feeding,**

In case of overdose, get medical help or contact a Poison Control Center right away. **Keep out of reach of children.**

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

years of age	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, edetate disodium, ethylcellulose, FD&C yellow no. 6, 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

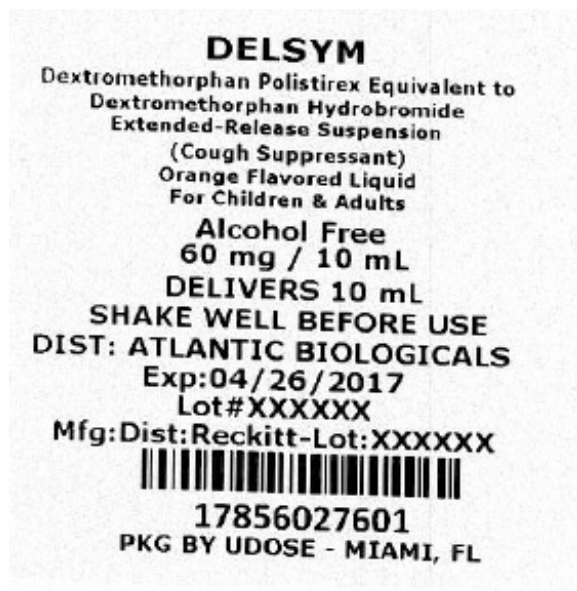
Questions?

1-888-963-3382

You may also report side effects to this phone number.

Distributed by: Reckitt Benckiser, Parsippany, NJ 07054-0224

DELSYM (DEXTROMETHORPHAN) (DEXTROMETHORPHAN) SUSPENSION, EXTENDED RELEASE



DELSYM (DEXTROMETHORPHAN)

dextromethorphan suspension, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0276(NDC:63824-177)
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)	
citric acid monohydrate (UNII: 2968PHW8QP)	
edetate disodium (UNII: 7FLD91C86K)	
ethylcelluloses (UNII: 7Z8S9VYZ4B)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
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		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0276-1	10 mL in 1 CUP; Type 0: Not a Combination Product	05/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018658	08/19/2011	

Labeler - Atlantic Biologicals Corps (047437707)

Registrant - Atlantic Biologicals Corps (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-0276) , REPACK(17856-0276)

Revised: 5/2016

Atlantic Biologicals Corps