DELSYM- dextromethorphan suspension, extended release
A-S Medication Solutions

DELSYM

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 such 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, 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

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, 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?

1-866-682-4639
You may also report side effects to this phone number.

Distributed by:
RB Health (US)
Parsippany, NJ
07054-0224

HOW SUPPLIED

Product: 50090-0224

NDC: 50090-0224-0 89 mL in a BOTTLE / 1 in a CARTON

Dextromethorphan

DELSYM

dextromethorphan suspension, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-0224(NDC:63824-175)
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)	
ETHYLCELLULOSE, UNSPECIFIED (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	ORANGE	**Score**	
Shape		**Size**	
Flavor	ORANGE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-0224-0	1 in 1 CARTON	11/28/2014	
1		89 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018658	05/04/2010	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-0224)

Revised: 10/2023 A-S Medication Solutions