# DELSYM - dextromethorphan suspension, extended release Physicians Total Care, Inc.

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Delsym 12 Hour Cough Relief Orange

**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	10 mL every 12 hours,
over	not to exceed 20 mL in 24 hours

children 6 to under 12 years of age	o hill every 12 hours,	
children o to under 12 years of age	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, polyethylene glycol 3350, polysorbate 80, propylene glycol, propylparaben, purified water, sucrose, tragacanth, vegetable oil, 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 ©RB 2011

#### Additional barcode labeling by:

Physicians Total Care, Inc. Tulsa, Oklahoma 74146

#### PRINCIPAL DISPLAY PANEL - 89 mL Bottle Carton

NDC 54868-6003-0

## **Dels ym**<sup>®</sup>

Dextromethorphan Polistirex Extended-Release Suspension (Cough Suppressant)

#### COUGH

DAY

OR

**NIGHT** 

12

**HOUR** 

**COUGH RELIEF** 

**Orange** 

Flavored Liquid

89 mL (3 fl oz)

Alcohol-free



#### **DELSYM**

dextromethorphan suspension, extended release

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54868-6003(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: 5H9 W9 GTW27)	
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: C151H8 M554)	
tragacanth (UNII: 2944357O2O)	
xanthan gum (UNII: TTV12P4NEE)	

#### **Product Characteristics**

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:54868-6003-0	1 in 1 CARTON		
1		89 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA0 18 6 58	03/13/2009	

## **Labeler -** Physicians Total Care, Inc. (194123980)

Establishment				
Name	Address	ID/FEI	Business Operations	
Physicians Total Care, Inc.		194123980	relabel(54868-6003)	

Revised: 8/2012 Physicians Total Care, Inc.