

**DELSYM- dextromethorphan suspension, extended release**  
**RB Health (US) LLC**

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

### PRINCIPAL DISPLAY PANEL - 148 mL Bottle Carton

NDC 63824-171-65

**Delsym®**

Dextromethorphan Polistirex  
 Extended-Release Suspension (Cough Suppressant)

**COUGH**

**12  
 HOUR  
 COUGH RELIEF®**

Day or Night

**Grape**

Flavored Liquid

**148 mL (5 fl oz)**

SULFITE FREE

ALCOHOL FREE

12 Hour  
Cough Relief

# Delsym

**COUGH**



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# Delsym

Dextromethorphan Polistirex  
Extended-Release Suspension (Cough Suppressant)

**COUGH**

### DELSYM® DOSING

SHAKE WELL BEFORE USE.  
Measure only with dosing cup provided.  
Do not use dosing cup with other products.

Age (yr)	Dose
12 years to adult	10 mL EVERY 12 HOURS
6 to under 12	5 mL EVERY 12 HOURS
4 to under 6	2.5 mL EVERY 12 HOURS
Under 4	Do not use

See back panel for full dosing directions.



**Dosing Cup Included**

Contains  
No Fever Reducer  
or Pain Reliever



Lot No.:

Exp. Date:

NO INK & COATING



71975M

TAMPER EVIDENT: Do not use if the neckband printed with [ ] is broken or missing.

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12 Hour Cough Relief

# Delsym

Dextromethorphan Polistirex  
Extended-Release Suspension (Cough Suppressant)

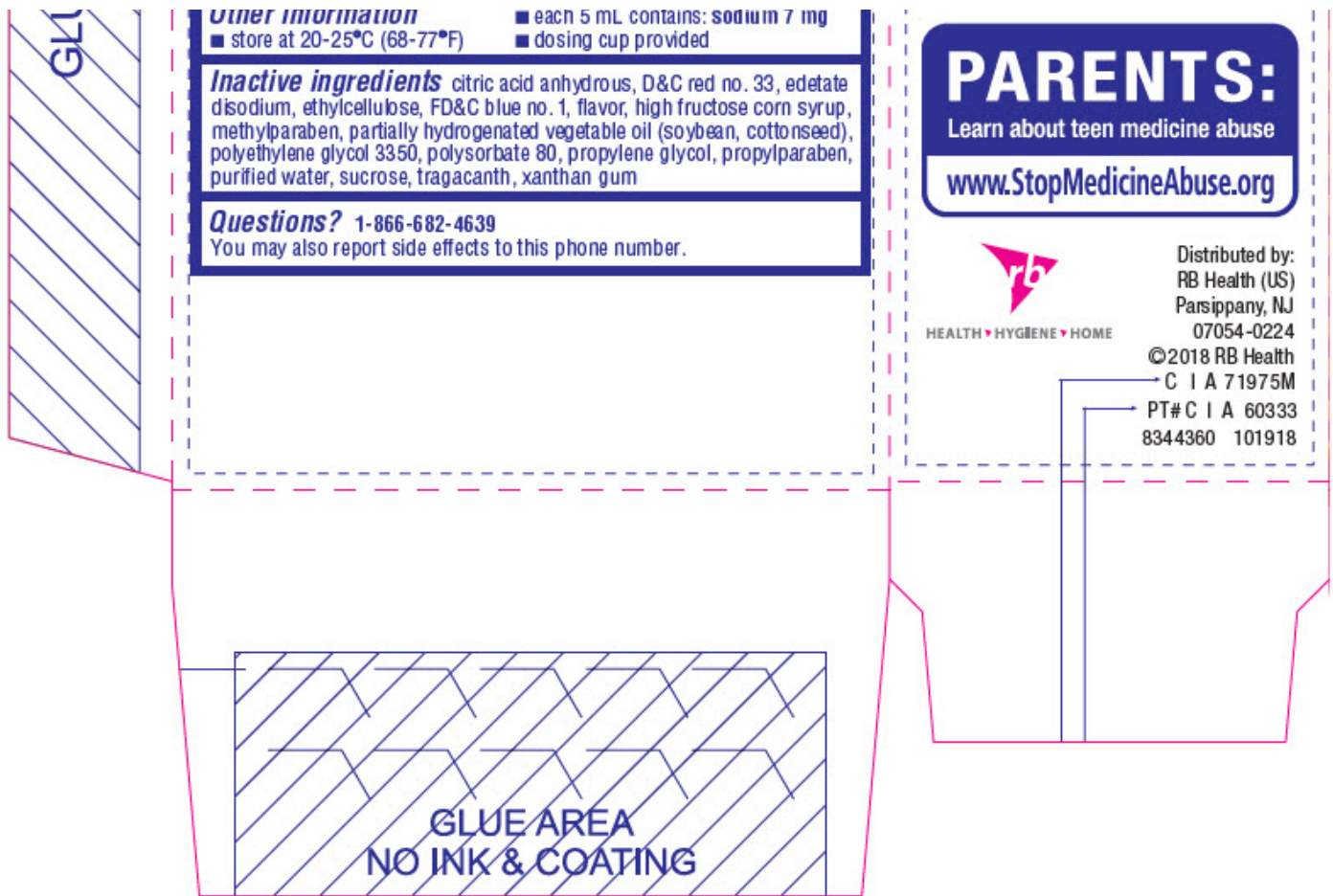
## COUGH

Also Available  
In Orange Flavor



Please visit  
our website:  
[www.delsym.com](http://www.delsym.com)

JE AREA - NO INK & COATING



## DELSYM

dextromethorphan suspension, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-171
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>Polistirex</b> (UNII: 5H9W9GTW27)	
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>D&amp;C Red NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>ethylcellulose, unspecified</b> (UNII: 7Z8S9VYZ4B)	
<b>FD&amp;C Blue NO. 1</b> (UNII: H3R47K3TBD)	

<b>high fructose corn syrup</b> (UNII: XY6UN3QB6S)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>polyethylene glycol 3350</b> (UNII: G2M7P15E5P)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>tragacanth</b> (UNII: 2944357O2O)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-171-63	1 in 1 CARTON	05/04/2010	
1		89 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:63824-171-65	1 in 1 CARTON	05/04/2010	
2		148 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
3	NDC:63824-171-75	1 in 1 CARTON	05/04/2010	
3		15 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
4	NDC:63824-171-22	2 in 1 CELLO PACK	05/04/2010	
4		1 in 1 CARTON		
4		148 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** - RB Health (US) LLC (081049410)