

**DELSYM (DEXTROMETHORPHAN)- dextromethorphan suspension, extended release**  
**Reckitt Benckiser LLC**

-----  
**Delsym® (Dextromethorphan) Suspension**  
**Extended-Release**

***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 |
|  | 5 mL every 12 hours, not to exceed 10 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?

**1-888-963-3382**

You may also report side effects to this phone number.

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

### PRINCIPAL DISPLAY PANEL - 148 mL Bottle Carton

NDC 63824-173-65

### Children's Delsym®

Dextromethorphan Polistirex  
Extended-Release Suspension (Cough Suppressant)

### COUGH

**Age 4+**

For  
Children  
& Adults

**12  
HOUR  
COUGH RELIEF**

**Grape**  
Flavored Liquid  
148 mL (5 fl oz)

Day or Night  
Alcohol-free

12 Hour  
Cough Relief

Children's  
**Delsym**

**COUGH**



**Grape**  
Flavored Liquid

NDC 63824-173-65

Children's  
**Delsym**

Dextromethorphan Polistirex  
Extended-Release Suspension (Cough Suppressant)

**COUGH**

Age **4+**

For  
Children  
& Adults



**Grape**  
Flavored Liquid

148 mL (5 fl oz)

Day or Night  
Alcohol-free

12 Hour Cough Relief

Children's  
**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.  
mL = milliliter

| Age (yr)          | Dose                     |
|-------------------|--------------------------|
| 12 years to adult | 10 mL<br>EVERY 12 HOURS  |
| 6 to under 12     | 5 mL<br>EVERY 12 HOURS   |
| 4 to under 6      | 2.5 mL<br>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

3-63824-27265-8  
(UPC @ 100% truncated)

Lot No.:

Exp. Date:

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

Code 128  
71978J

## Drug Facts

### Active ingredient (in each 5 mL)

Dextromethorphan polistirex equivalent to  
30 mg dextromethorphan hydrobromide.....Cough suppressant

### Purpose

### 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

## 12 Hour Cough Relief

Children's  
**Delsym**

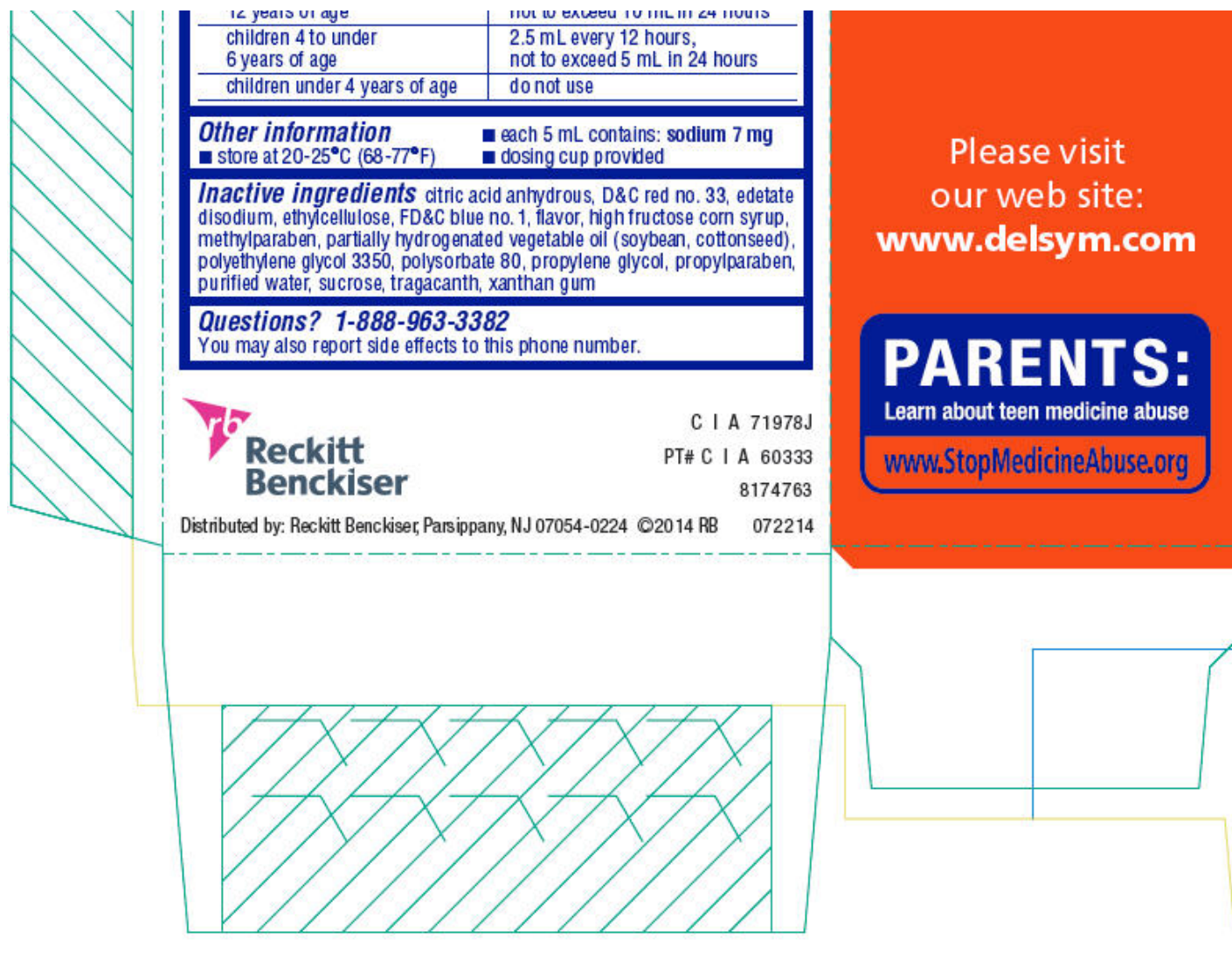
Dextromethorphan Polistirex  
Extended-Release Suspension (Cough Suppressant)

**COUGH**

**Also Available  
In Orange Flavor**







## DELSYM (DEXTROMETHORPHAN)

dextromethorphan suspension, extended release

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63824-173 |
| <b>Route of Administration</b> | 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)         |  |
| ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)          |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)          |  |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) |  |
| METHYL PARABEN (UNII: A2I8C7HI9T)           |  |
| POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) |  |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)           |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)         |  |
| PROPYL PARABEN (UNII: Z8IX2SC1OH)           |  |
| WATER (UNII: 059QF0KO0R)                    |  |
| SUCROSE (UNII: C15IH8M554)                  |  |
| TRAGACANTH (UNII: 2944357O2O)               |  |
| XANTHAN GUM (UNII: TTV12P4NEE)              |  |

### Product Characteristics

|          |       |              |  |
|----------|-------|--------------|--|
| Color    |       | Score        |  |
| Shape    |       | Size         |  |
| Flavor   | GRAPE | Imprint Code |  |
| Contains |       |              |  |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63824-173-63 | 1 in 1 CARTON   |                      |                    |
| 1 |                  | 89 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)  |                      |                    |
| 2 | NDC:63824-173-65 | 1 in 1 CARTON   |                      |                    |
| 2 |                  | 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                                | 08/19/2011           |                    |

**Labeler** - Reckitt Benckiser LLC (094405024)