

DELSYM (DEXTROMETHORPHAN)- dextromethorphan suspension, extended release

Reckitt Benckiser LLC

Delsym[®] Extended-Release Suspension

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 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 63824-173-65

Ages 4+

Children's
Delsym[®]

Dextromethorphan Polistirex
Extended-Release Suspension (Cough Suppressant)

COUGH

Day
or
Night

12
HOUR

COUGH RELIEF™

Grape
Flavored Liquid

148 mL (5 fl oz)

For Children & Adults

12 Hour
Cough Relief

Children's

Delsym

COUGH



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TM



12 Hour Cough Relief

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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



71978M

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

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|--|-------------------|
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12 Hour Cough Relief
 Children's
Delsym

Dextromethorphan Polistirex
 Extended-Release Suspension (Cough Suppressant)

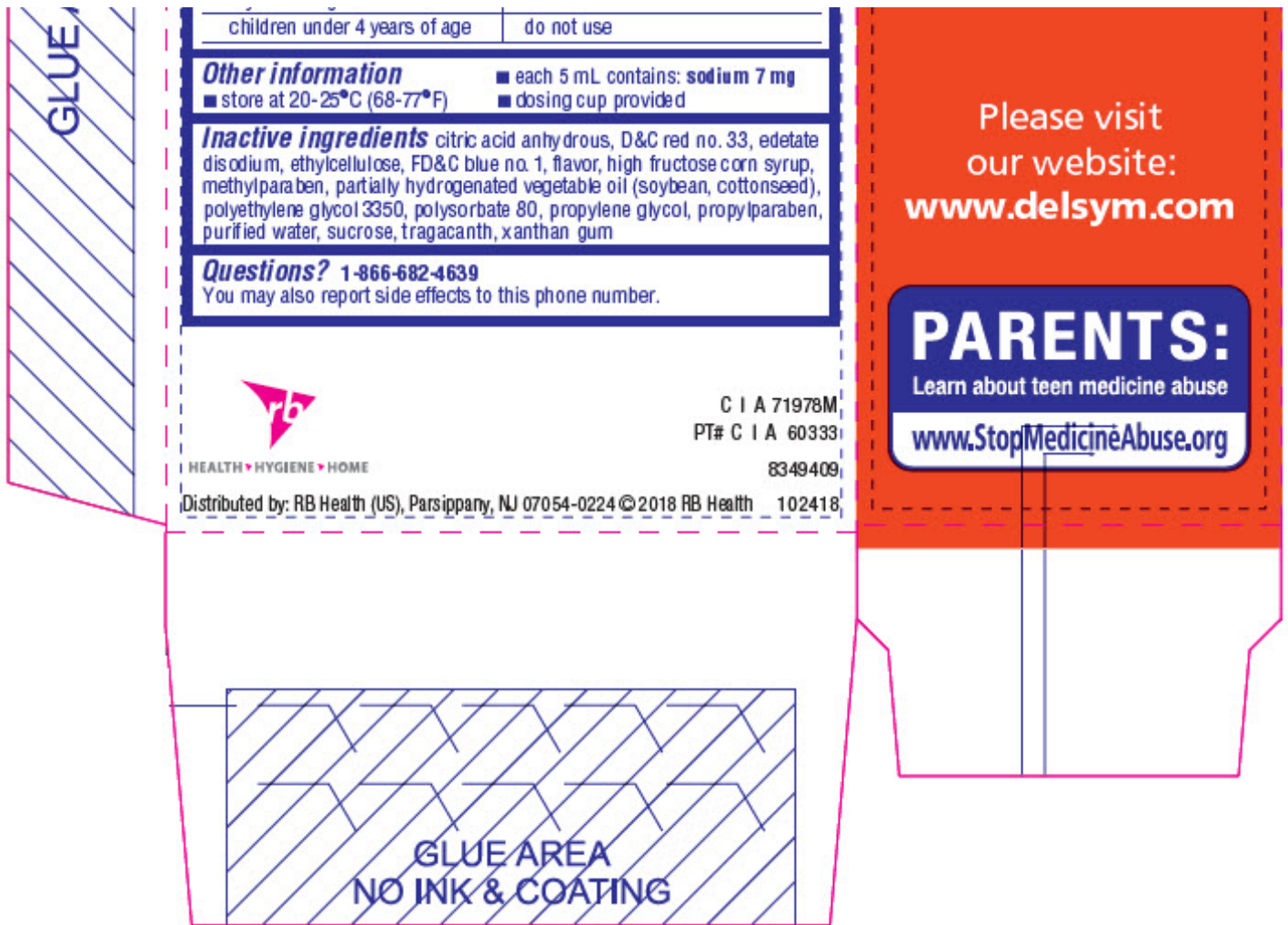
COUGH

ALCOHOL FREE Sulfite Free

Also Available
In Orange Flavor



AREA - NO INK & COATING



DELSYM (DEXTROMETHORPHAN)

dextromethorphan suspension, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63824-173 |
| 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) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |

| | |
|---|--|
| ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| 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 | GRAPE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63824-173-63 | 1 in 1 CARTON | 08/19/2011 | |
| 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 | 08/19/2011 | |
| 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)