

DELSYM (DEXTROMETHORPHAN)- dextromethorphan suspension, extended release

RB Health (US) 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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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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12 Hour Cough Relief
 Children's
Delsym

Dextromethorphan Polistirex
Extended-Release Suspension (Cough Suppressant)

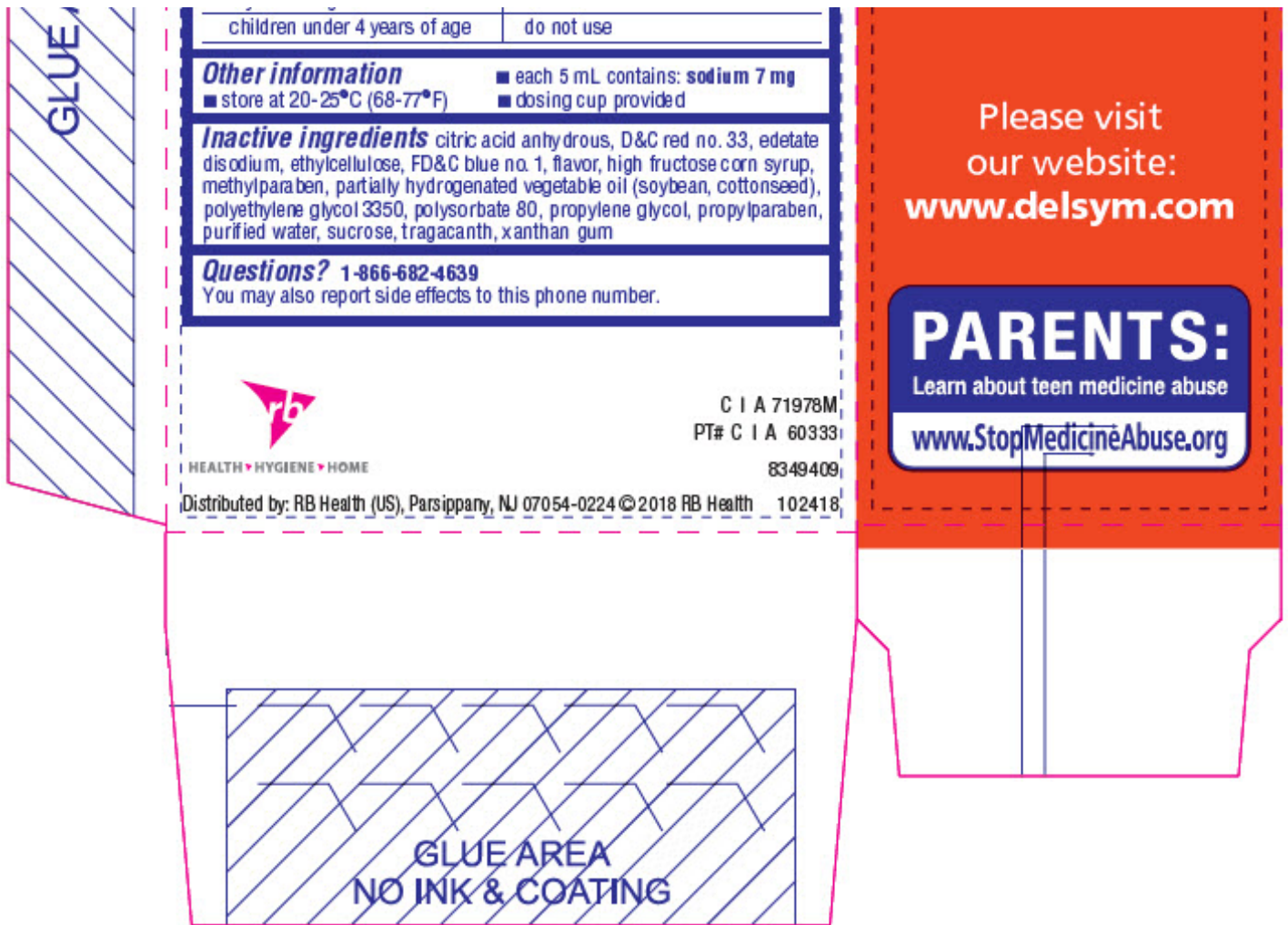
COUGH

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 - RB Health (US) LLC (081049410)