

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

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 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, edetate disodium, ethylcellulose, FD&C yellow no. 6, 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 63824-175-65

Delsym®

Dextromethorphan Polistirex
 Extended-Release Suspension (Cough Suppressant)

COUGH

12
HOUR
COUGH RELIEF

Orange
Flavored Liquid

148 mL (5 fl oz)

Day or Night
SULFITE FREE
ALCOHOL FREE

12 Hour
Cough Relief

Delsym

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COUGH

DELSYM® DOSING

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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



70235S

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

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Extended-Release Suspension (Cough Suppressant)

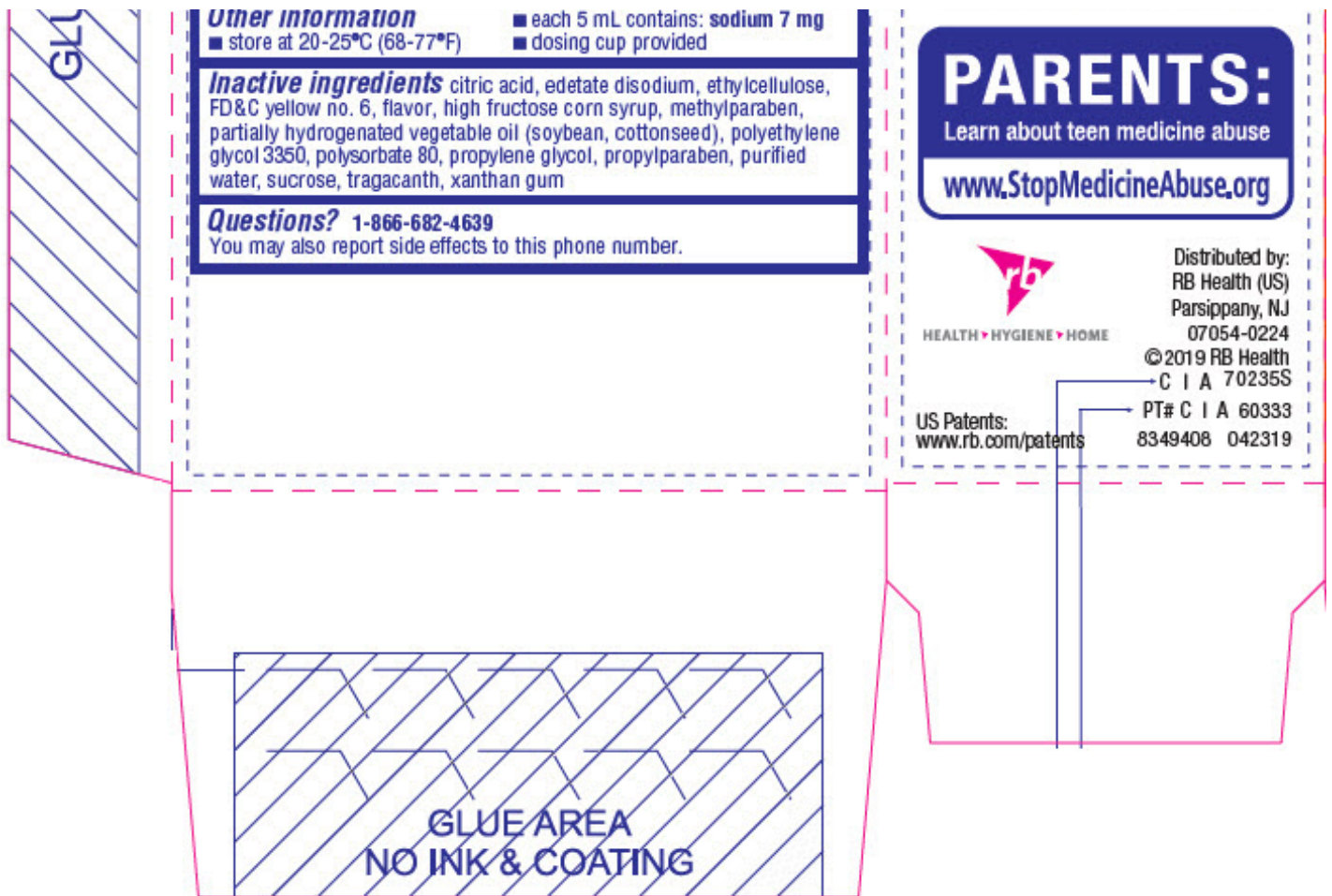
COUGH

Also Available
In Grape Flavor



Please visit
our website:
www.delsym.com

JE AREA - NO INK & COATING



DELSYM
dextromethorphan suspension, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	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: 5H9W9GTW27)	
citric acid monohydrate (UNII: 2968PHW8QP)	
edetate disodium (UNII: 7FLD91C86K)	
ETHYLCELLULOSE, UNSPECIFIED (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: C151H8M554)	
tragacanth (UNII: 2944357O2O)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-175-63	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:63824-175-65	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:63824-175-75	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:63824-175-22	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)