

**DELSYM COUGH PLUS CHEST CONGESTION DM- dextromethorphan hydrobromide and guaifenesin solution**

**RB Health (US) LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Delsym®**

**Cough Plus™ Chest Congestion DM**

***Drug Facts***

<b><i>Active ingredients (in each 20 mL)</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - 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**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

**When using this product do not use more than directed**

**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**

- do not take more than 6 doses in any 24-hour period
- 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: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

### Other information

- each 20 mL contains: **sodium 12 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

### Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate<sup>1</sup>, xanthan gum

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<sup>1</sup> may contain this ingredient

### Questions?

**1-866-682-4639**

You may also report side effects to this phone number.

Dist. by: RB Health (US)

Parsippany, NJ 07054-0224

### PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label

NDC 63824-213-66

Delsym®

COUGH+™

CHEST

CONGESTION

DM

Dextromethorphan HBr (Cough Suppressant)

Guaifenesin (Expectorant)

- Controls Cough
- Relieves Chest Congestion
- Thins & Loosens Mucus

6 fl oz (180 mL)

For Ages 12+

Cherry

Flavored Liquid

042619

3096403

NDC 63824-213-66

# Delsym<sup>®</sup>

042619 3096403

**COUGH**  **TM CHEST CONGESTION**

## DM

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#### Warnings

### Drug Facts (continued)

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products

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**Inactive ingredients**

anhydrous citric acid, edetate

PEEL HERE

**Drug Facts (continued)**

disodium, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate\*, xanthan gum

\*may contain this ingredient

**Questions?**

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US patents: [www.rb.com/patents](http://www.rb.com/patents)

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

PEEL CORNER TO READ COMPLETE  
DRUG FACTS AND INFORMATION

Maximum Strength per 4-hour dose  
Tamper evident: Do not use if neckband  
on bottle cap is broken or missing.

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



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Parsippany, NJ 07054-0224  
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041219

LOT:

3070202

EXP:

MADE IN:

**DELSYM COUGH PLUS CHEST CONGESTION DM**

dextromethorphan hydrobromide and guaifenesin solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-213
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RT9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	20 mg in 20 mL
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg in 20 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C Red No. 40</b> (UNII: WZB9127XOA)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>propyl gallate</b> (UNII: 8D4SNN7V92)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>trisodium citrate dihydrate</b> (UNII: B22547B95K)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-213-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/31/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/31/2013	

**Labeler** - RB Health (US) LLC (081049410)

