

**DELSYM COUGH PLUS SOOTHING ACTION- dextromethorphan hydrobromide and menthol lozenge**

**Reckitt Benckiser 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™ Soothing Action**

***Drug Facts***

<b><i>Active ingredients (in each lozenge)</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr 5 mg	Cough suppressant
Menthol 5 mg	Oral pain reliever

**Uses**

temporarily relieves

- sore throat
- sore mouth
- minor mouth irritation
- cough due to minor throat and bronchial irritation as may occur with the common cold

**Warnings**

**Sore throat warning**

- If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly.

**Do not use** in a child under 6 years of age.

**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, or emphysema
- cough that occurs with too much phlegm (mucus)

**Stop use and ask a doctor or dentist if**

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling develops
- 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**

- adults and children 12 years and older: take 2 lozenges (one immediately after the other) and allow each lozenge to dissolve slowly in the mouth; may be repeated every 4 hours, not to exceed 12 lozenges in any 24-hour period, or as directed by a doctor
- children 6 to under 12 years of age: take 1 lozenge and allow to dissolve slowly in the mouth; may be repeated every 4 hours, not to exceed 6 lozenges in 24 hours, or as directed by a doctor
- children under 6 years of age: do not use

### **Other information**

- tamper evident: product is sealed in blister package for your protection. Do not use if carton is damaged or if printed seal on blister is broken or missing.
- store between 20-25°C (68-77°F)

### **Inactive ingredients**

D&C Yellow #10, FD&C Yellow #6, flavors, liquid glucose, propylene glycol, sucralose, sucrose, water

### **Questions?**

**Call 1-888-963-3382**

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser  
Parsippany, NJ 07054-0224  
Made in England

### **PRINCIPAL DISPLAY PANEL - 16 Lozenge Carton**

**NDC 63824-164-16**

**Delsym®**

**COUGH +™  
SOOTHING  
ACTION**

**LOZENGES**

Dextromethorphan HBr 5 mg (Cough Suppressant)  
Menthol 5 mg (Oral Pain Reliever)

- **Quiets Cough**
- **Relieves Sore Throat**
- **Soothing Action**

**16 LOZENGES**

**Honey  
Lemon**



# Delsym

**COUGH + SOOTHING ACTION**

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NDC 63824-164-16

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**COUGH + SOOTHING ACTION**

**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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

**COUGH + SOOTHING ACTION**

**Delsym**  
Dextromethorphan HBr 5 mg (Cough Suppressant)  
Menthol 5 mg (Oral Pain Reliever)

**Drug Facts**

**Active ingredients (in each lozenge)**

Dextromethorphan HBr 5 mg...Cough suppressant  
Menthol 5 mg.....Oral pain reliever

**Purposes**

**Uses** temporarily relieves ■ sore throat  
■ sore mouth ■ minor mouth irritation  
■ cough due to minor throat and bronchial irritation as may occur with the common cold

**Warnings**

**Sore throat warning**  
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**Drug Facts (continued)**

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Dist. by: Reckitt Benckiser  
Parsippany, NJ 07054-0224 040513  
Made in England ©2013 RB 8089693

	Lane 1	Lane 1
Lot No.:	Lane 2	Lane 2
Exp. Date:	Lane 3	Lane 3

8089693

**DELSYM COUGH PLUS SOOTHING ACTION**

dextromethorphan hydrobromide and menthol lozenge

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63824-164

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	5 mg
<b>Menthol</b> (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>water</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	YELLOW	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	20mm
<b>Flavor</b>	HONEY, LEMON	<b>Imprint Code</b>	S
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-164-16	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/12/2013	

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

Revised: 5/2013

Reckitt Benckiser LLC