

**DELSYM COUGH RELIEF 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 Relief Plus Soothing Action**

**Drug Facts**

<b>Active ingredients (in each lozenge)</b>	<b>Purpose</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 is accompanied by excessive 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 persistent headache. These could be signs of a serious illness

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep this and all drugs out of the 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 at room temperature 20-25°C (68-77°F)

**Inactive ingredients**

D&C red #33, FD&C red #40, flavors, isomalt, maltitol syrup, propylene glycol, sorbitol, sucralose, 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

**PRINCIPAL DISPLAY PANEL - 16 Lozenge Blister Pack**

**NDC 63824-161-16**

***NEW!***

**Delsym<sup>®</sup>**

**COUGH RELIEF *PLUS***  
***SOOTHING ACTION***

Dextromethorphan HBr 5 mg (Cough Suppressant)

Menthol 5 mg (Oral Pain Reliever)

- **Quiets cough**
- **Relieves sore throat**
- **Soothing action**

**16 LOZENGES**

**Sugar Free**  
**Cherry**



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**COUGH RELIEF PLUS**  
*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)

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SOOTHING ACTION

**Delsym**

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

## Drug Facts

### Active ingredients Purpose (in each lozenge)

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

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## Drug Facts (continued)

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**Reckitt Benckiser**

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

010412  
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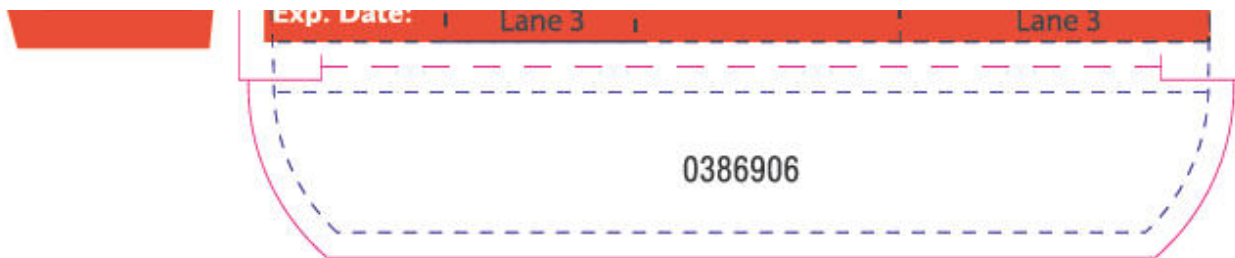
Lot No.:

Lane 1

Lane 2

Lane 1

Lane 2



## DELSYM COUGH RELIEF PLUS SOOTHING ACTION

dextromethorphan hydrobromide and menthol lozenge

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-161
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg

### Inactive Ingredients

Ingredient Name	Strength
D&C red no. 33 (UNII: 9DBA0SBB0L)	
FD&C red no. 40 (UNII: WZB9127XOA)	
isomalt (UNII: S870P55O2W)	
propylene glycol (UNII: 6DC9Q167V3)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
water (UNII: 059QF0KO0R)	

### Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	27mm
Flavor	CHERRY	Imprint Code	D
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-161-16	16 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/01/2012	

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

Revised: 3/2012

Reckitt Benckiser LLC