

**CHILDRENS MUCINEX CONGESTION AND COUGH- dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride 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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**Children's Mucinex®**  
**Congestion & Cough**

***Drug Facts***

<b><i>Active ingredients (in each 5 mL)</i></b>	<b><i>Purpose</i></b>
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 2.5 mg	Nasal decongestant

**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 your child get to sleep
  - nasal congestion due to a cold
  - stuffy nose

**Warnings**

**Do not use** in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if the child has**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

**When using this product**

- **do not use more than directed**

**Stop use and ask a doctor if**

- your child gets nervous, dizzy or sleepless
- symptoms do not get better within 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

**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
- mL = milliliter

Age	Dose
children 6 years to under 12 years	10 mL every 4 hours
children 4 years to under 6 years	5 mL every 4 hours
children under 4 years	do not use

### Other information

- each 5 mL contains: **sodium 3 mg**
- tamper evident: do not use if neckband on bottle cap is broken or missing
- store between 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

### Inactive ingredients

anhydrous citric acid, D&C red #33, dextrose, FD&C blue #1, FD&C red #40, flavors, glycerin, methylparaben, potassium sorbate, propyl gallate, propylene glycol, propylparaben, purified water, saccharin sodium, sodium hydroxide, sorbitol, sucralose, xanthan gum

### Questions?

**1-866-MUCINEX (1-866-682-4639)** You may also report side effects to this phone number.

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

Made in England

### PRINCIPAL DISPLAY PANEL - 201 mL Bottle Carton

#### **VALUE SIZE!**

NDC 63824-279-67

Children's  
**Mucinex®**

### **Congestion & Cough**

Guaifenesin 100 mg	Expectorant
Dextromethorphan HBr 5 mg	Cough Suppressant
Phenylephrine HCl 2.5 mg	Nasal Decongestant

- ▣ **Chest Conges tion**
- ▣ **Breaks up Mucus**
- ▣ **Stuff Nose**
- ▣ **Cough**

**Berrylicious  
Flavor Liquid**

**6.8 FL OZ  
(201 mL)**

Tamper evident: do not use if neckband on bottle cap is broken or missing.

# Children's MucinEX®

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- ✓ Chest Congestion
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- ✓ Stuffy Nose
- ✓ Cough



**Berrylicious  
Flavor Liquid**

# Children's MucinEX®

## Congestion & Cough



**DOSING CUP INCLUDED**

Each dose of berrylicious-flavored MucinEX® Congestion & Cough Liquid:

- ✓ Relieves Chest Congestion
- ✓ Breaks up Mucus
- ✓ Relieves Stuffy Nose



6.8 FL OZ  
(201 mL)

✓ Controls Cough

**Questions or comments?**  
1-866-MUCINEX (1-866-682-4639)  
or [www.mucinex.com](http://www.mucinex.com)



LOT CODE:

EXP. DATE:

8021397

**Drug Facts (continued)**

**Inactive Ingredients** anhydrous citric acid, D&C red #33, dextrose, FD&C blue #1, FD&C red #40, flavors, glycerin, methylparaben, potassium sorbate, propyl gallate, propylene glycol, propylparaben, purified water, saccharin sodium, sodium hydroxide, sorbitol, sucralose, xanthan gum

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**PARENTS:**

Learn about teen medicine abuse

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

Also look for

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Children's  
**MucinEX**



Great-tasting  
chest-congestion relief in  
fun-to-take, convenient  
granule packets!

Dist. by: Reckitt Benckiser  
Parsippany, NJ 07054-0224 ©2012 RB  
Made in England 050112

 **Reckitt  
Benckiser**  
8021397

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dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:638 24-279
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>D&amp;C red no. 33</b> (UNII: 9DBA0SBB0L)	
<b>dextrose, unspecified form</b> (UNII: IY9XDZ35W2)	
<b>FD&amp;C blue no. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C red no. 40</b> (UNII: WZB9127XOA)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>potassium sorbate</b> (UNII: 1VPU26JZZ4)	
<b>propyl gallate</b> (UNII: 8D4SNN7V92)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>saccharin sodium</b> (UNII: SB8ZUX40TY)	
<b>sodium hydroxide</b> (UNII: 55X04QC32I)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>sucralose</b> (UNII: 96K6UQ3ZD4)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-279-67	1 in 1 CARTON	06/10/2012	
1		201 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
OTC MONOGRAPH FINAL	part341	06/10/2012	

