

**MUCINEX CHILDRENS STUFFY NOSE AND CHEST CONGESTION- 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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**Mucinex® Children's  
Stuffy Nose & Chest Congestion**

**Drug Facts**

<b>Active ingredients (in each 5 mL)</b>	<b>Purposes</b>
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:
  - 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**

- nervousness, dizziness, or sleeplessness occur
- 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 condition.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

- do not give 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

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

### Other information

- each 5 mL contains: **sodium 3 mg**
- store between 20-25°C (68-77°F)
- do not refrigerate

### Inactive ingredients

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

1 may contain this ingredient

### Questions?

**1-866-MUCINEX (1-866-682-4639)**

You may also report side effects to this phone number.

Dist. by: RB Health (US)  
Parsippany, NJ 07054-0224

Made in England

**PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton**

Pediatrician Recommended<sup>†</sup>

NDC 63824-951-07

Mucinex®  
Children's

STUFFY NOSE &  
CHEST CONGESTION

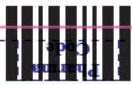
Guaifenesin 100 mg - Expectorant  
Phenylephrine HCl 2.5 mg - Nasal Decongestant

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

Ages  
4+  
yrs

Very Berry  
Flavor Liquid

4 FL OZ (118 mL)



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**Directions**

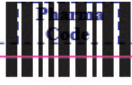
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**Drug Facts (continued)**

**Inactive ingredients** anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate\*, xanthan gum \*may contain this ingredient

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

\*as an OTC brand in the Children's Cough/Cold category (AlphaImpactRxProVoice Survey)

Other convenient forms for Chest Congestion Relief



On-the-go granule packets for chest congestion relief!

Keep carton for full information

Tamper evident: Do not use if neck band on bottle cap is broken or missing.



STUFFY NOSE & CHEST CONGESTION

Guaifenesin 100 mg - Expectorant  
Phenylephrine HCl 2.5 mg - Nasal Decongestant

Pediatrician Recommended\*

NDC 63824-951-07



STUFFY NOSE & CHEST CONGESTION

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Phenylephrine HCl 2.5 mg - Nasal Decongestant

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



Ages 4+ yrs

Very Berry Flavor Liquid

4 FL OZ (118 mL)



STUFFY NOSE & CHEST CONGESTION

Each dose of Very Berry flavored Mucinex Children's Stuffy Nose & Chest Congestion Liquid:

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



Dosing Cup Included

Questions or comments?  
1-866-Mucinex (1-866-682-4639)  
or www.mucinex.com

Dist by: RB Health (US)  
Parsippany, NJ 07054-0224  
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Made in Mexico  
012221 3163776



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LOT CODE:  
EXP. DATE:

# MUCINEX CHILDRENS STUFFY NOSE AND CHEST CONGESTION

guaifenesin and phenylephrine hydrochloride solution

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-951
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Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<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>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-951-07	1 in 1 CARTON	05/01/2018	
1		118 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	05/01/2018	

