

**MUCINEX CHILDRENS NIGHT TIME MULTI-SYMPTOM COLD- acetaminophen, diphenhydramine hydrochloride, 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**  
**Night Time Multi-Symptom Cold**

***Drug Facts***

<b><i>Active ingredients (in each 10 mL)</i></b>	<b><i>Purposes</i></b>
<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - runny nose
  - sneezing
  - cough
- controls cough to help your child get to sleep
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**Allergy alert**

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- to make a child sleepy
- with any other product containing diphenhydramine, even one used on the skin
- 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**

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

### **Ask a doctor or pharmacist before use if the child is**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

- **do not use more than directed (see Overdose warning)**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

### **Keep out of reach of children.**

### **Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

### **Directions**

- **this product does not contain directions or complete warnings for adult use**

- **do not give more than directed (see Overdose warning)**
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours while symptoms last; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

### Other information

- each 10 mL contains: **sodium 6 mg**
- store between 20-25°C (68-77°F)
- do not refrigerate

### Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue no. 1, 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

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<sup>1</sup> 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 63824-950-21

Mucinex®

Children's

NIGHT TIME

MULTI-SYMPTOM

COLD

Acetaminophen 325 mg - Pain Reliever/Fever Reducer

Diphenhydramine HCl 12.5 mg - Antihistamine/Cough Suppressant

Phenylephrine HCl 5 mg - Nasal Decongestant

- Relieves Stuffy Nose
- Controls Cough
- Relieves Runny Nose & Sneezing
- Relieves Fever & Sore Throat

Ages

6<sup>+</sup>

yrs

Very Berry

Flavor Liquid

4 FL OZ (118 mL)

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

**Mucinex**  
Children's

 **NIGHT TIME**  
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**Drug Facts** (continued)

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\*may contain this ingredient



**Questions?** 1-866-MUCINEX (1-866-682-4639)  
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†as an OTC brand in the Children's  
Cough/Cold category  
(AlphalmpactRxProVoice Survey)

Keep carton for full information.



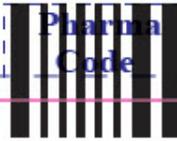
Ages **6+** yrs

**Very Berry**  
Flavor Liquid

**4 FL OZ (118 mL)**



LOT CODE:  
EXP. DATE:



**Mucinex**

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Children's



# NIGHT TIME MULTI-SYMPTOM COLD

Each dose of Very Berry flavored  
Mucinex Children's Night Time  
Multi-Symptom Cold Liquid:

- ✓ Relieves Stuffy Nose
- ✓ Controls Cough
- ✓ Relieves Runny Nose & Sneezing
- ✓ Relieves Fever & Sore Throat



## Dosing Cup Included

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

Dist. by: RB Health (US)  
Parsippany, NJ 07054-0224  
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Made in Mexico  
100518 3078367



HEALTH > HYGIENE > HOME

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## MUCINEX CHILDRENS NIGHT TIME MULTI-SYMPTOM COLD

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-950
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	12.5 mg in 10 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	BLUE	<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
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1	NDC:63824-950-21	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)		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341		05/01/2018	

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

Revised: 1/2019

RB Health (US) LLC