

**MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD, FLU AND SORE THROAT AND MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride  
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.*

-----  
**Mucinex® Children's FreeFrom Multi-Symptom Cold, Flu & Sore Throat and Mucinex® Children's FreeFrom Multi-Symptom Cold & Flu Nighttime**

**DAYTIME MULTI-SYMPTOM COLD, FLU & SORE THROAT - Ages 6+ YRS.**

***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>
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - stuffy nose
  - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**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.
- 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
- 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

**When using this product do not use more than directed (see Overdose warning)**

### **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 at 20-25°C (68-77°F)
- do not refrigerate

### Inactive ingredients

ammonium glycyrrhizate, anhydrous citric acid, cochineal carmine, edetate disodium, flavors, glycerin (soy), maltodextrin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### Questions?

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

**MULTI-SYMPTOM COLD & FLU NIGHTTIME - Ages 6+ YRS.**

### Drug Facts

<b>Active ingredients (in each 10 mL)</b>	<b>Purposes</b>
<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant
Triprolidine HCl 1.25 mg	Antihistamine

### Uses

- temporarily relieves these common cold and flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion

- runny nose
- sneezing
- cough
- stuffy nose
- temporarily reduces fever
- controls cough to help your child get to sleep

## **Warnings**

### **Liver warning**

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

- more than 1625 mg 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
- 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
- may cause marked drowsiness
- 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 4 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 at 20-25°C (68-77°F)
- do not refrigerate

### **Inactive ingredients**

ammonium glycyrrhizate, anhydrous citric acid, cochineal carmine, edetate disodium, flavors, glycerin (soy), maltodextrin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

## **Questions?**

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

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

Made in Mexico

## **PRINCIPAL DISPLAY PANEL - Kit Carton**

Pediatrician Recommended †

NDC 63824-960-24

VALUE PACK

DAYTIME

NIGHTTIME

Mucinex®

Children's

FREEFROM

MULTI-SYMPTOM

COLD, FLU

& SORE THROAT

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

DEXTROMETHORPHAN HBr – COUGH SUPPRESSANT

GUAIFENESIN – EXPECTORANT

PHENYLEPHRINE HCl – NASAL DECONGESTANT

MULTI-SYMPTOM

COLD & FLU

NIGHTTIME

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

# DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT

# PHENYLEPHRINE HCl - NASAL DECONGESTANT

# TRIPROLIDINE HCl - ANTIHISTAMINE

# FREEFROM

# ARTIFICIAL FLAVORS, COLORS, & DYES • ALCOHOL & SUGAR

# ELDERBERRY

# & CHERRY NATURAL FLAVOR

# AGES 6+ YRS.

4 FL OZ (118 mL)

8 FL OZ (236 mL) TOTAL

4 FL OZ (118 mL)

**5/8** **4 1/16** **2 1/32** **4 1/16** **2**

**5** **45** **64**

**19 25/32**

**MIN PT. SIZE & Drug Facts Table**

**NET WT (e): 3 FL OZ 118 mL**

**Active Ingredients Table:**

Active Ingredients	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant
Triprolidine HCl 2 mg	Antihistamine

# MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD, FLU AND SORE THROAT AND MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-960
---------------------	----------------	---------------------------	---------------

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-960-24	1 in 1 CARTON; Type 0: Not a Combination Product	06/15/2020	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE	118 mL

## Part 1 of 2

**MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD, FLU AND**



# SORE THROAT

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

## Product Information

**Route of Administration** ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARMINIC ACID</b> (UNII: CID8Z8N95N)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<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>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		1 in 1 CARTON		
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2020	

## Part 2 of 2

### MUCINEX CHILDRENS FREEFROM MULTI-SYMPTOM COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution

## Product Information

**Route of Administration** ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL
<b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARMINIC ACID</b> (UNII: CID8Z8N95N)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<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>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

**Color** red **Score**

<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		1 in 1 CARTON		
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2020	

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

Revised: 5/2022

RB Health (US) LLC