

**MUCINEX CHILDRENS MULTI-SYMPTOM COLD AND SORE THROAT-
acetaminophen, 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.

**Mucinex Children's
Multi-Symptom Cold & Sore Throat**

Drug Facts

<i>Active ingredients (in each 10 mL)</i>	<i>Purposes</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
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:
 - nasal congestion
 - stuffy nose
 - cough due to minor throat and bronchial irritation
 - the intensity of coughing
 - the impulse to cough to help your child get to sleep
 - minor aches and pains
 - sore throat
 - headache
- 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
- high blood pressure
- thyroid disease
- diabetes
- 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 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 dihydrate¹, 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^f

NDC 63824-952-17

**Mucinex®
Children's**

**MULTI-SYMPTOM
COLD &
SORE THROAT**

Acetaminophen 325 mg - Pain Reliever/Fever Reducer

Dextromethorphan HBr 10 mg - Cough Suppressant
Guaifenesin 200 mg - Expectorant
Phenylephrine HCl 5 mg - Nasal Decongestant

- ✓ **Relieves Sore Throat**
- ✓ **Relieves Stuffy Nose**
- ✓ **Relieves Chest Congestion and Cough**
- ✓ **Breaks up Mucus**

Ages

6⁺

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

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Ages **6+** yrs

Very Berry
Flavor Liquid

Drug Facts (continued)

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*may contain this ingredient

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†as an OTC brand in the Children's Cough/Cold

category (AlphaImpactRxProVoice Survey)

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Keep carton for full information.



4 FL OZ (118 mL)



3 63824 27864 3

LOT CODE:

EXP. DATE:



Pharmacy
Code

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Children's

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 - minor aches and pains
 - sore throat
 - stuffy nose
 - headache

SORE THROAT

Each dose of Very Berry flavored Mucinex Children's Multi-Symptom Cold & Sore Throat Liquid:

- ✓ Relieves Sore Throat
- ✓ Relieves Stuffy Nose
- ✓ Relieves Chest Congestion and Cough
- ✓ Breaks up Mucus



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
110118 3078385



HEALTH • HYGIENE • HOME

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MUCINEX CHILDRENS MULTI-SYMPTOM COLD AND SORE THROAT

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-952
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 10 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 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: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
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			
Color	BLUE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-952-17	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	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022

RB Health (US) LLC