MUCINEX CHILDRENS COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution RB Health (US) LLC

Mucinex® Children's Cold & Flu

Drug Facts

Active ingredients (in each 10 mL)	Purposes	
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:
 - 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
- 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 at 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 ¹, 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 Mexico

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

Pediatrician Recommended †

NDC 63824-954-04

Mucinex® Children's

COLD & FLU

Acetaminophen 325 mg - Pain Reliever/Fever Reducer Dextromethorphan HBr 10 mg - Cough Suppressant Guaifenesin 200 mg - Expectorant Phenylephrine HCl 5 mg - Nasal Decongestant

HEADACHE SORE THROAT CHEST CONGESTION BODY PAIN FEVER COUGH NASAL CONGESTION SINUS CONGESTION SINUS PRESSURE ALL IN ONE*

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.



COLD & FLU

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Each dose of Very Berry flavored Mucinex Children's Cold & Flu Liquid temporarily relieves:







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 ©2020 RB Health Made in Mexico



021221 3163801 US Patents: www.rb.com/patents



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Drug Facts (continued)

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

tas an OTC brand in the Children's Cough/Cold category (AlphalmpactRxProVoice Survey) *Helps to relieve these symptoms day or night



Keep carton for full information.



MUCINEX CHILDRENS COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-954
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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)		
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			
Color	blue	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63824- 954-04	1 in 1 CARTON	04/01/2019		
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 Drug	M012	04/01/2019	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2024 RB Health (US) LLC