

MUCINEX CHILDRENS COUGH- dextromethorphan hydrobromide and guaifenesin 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 Cough

Drug Facts

Active ingredients (in each 5 mL)	Purposes
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help your child get to sleep

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

- 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 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 years to under 12 years of age	5 mL – 10 mL every 4 hours
children 4 years to under 6 years of age	2.5 mL – 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 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[†]

NDC 63824-946-03

Mucinex®
Children's

COUGH

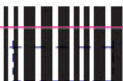
Dextromethorphan HBr 5 mg - Cough Suppressant
Guaifenesin 100 mg - Expectorant

- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ Breaks up Mucus

Ages
4+ yrs

Cherry
Flavor Liquid

4 FL OZ (118 mL)



2083912

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Drug Facts (continued)

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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

Other convenient forms for
Chest Congestion Relief

Mucinex[®]
Children's**CHEST CONGESTION**

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

Keep carton for full information

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

Mucinex[®]
Children's**COUGH**Dextromethorphan HBr 5 mg – Cough Suppressant
Guaifenesin 100 mg – Expectorant

Pediatrician Recommended*

NDC 63824-946-03

Mucinex[®]
Children's**COUGH**Dextromethorphan HBr 5 mg – Cough Suppressant
Guaifenesin 100 mg – Expectorant

- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ Breaks up Mucus

**Mucinex[®]**
Children's**COUGH**Each dose of Cherry flavored
Mucinex Children's Cough Liquid:

- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ 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
030521 3103802



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3163802



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LOT CODE:
EXP. DATE:

MUCINEX CHILDRENS COUGH

dextromethorphan hydrobromide and guaifenesin solution

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:63824-946

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)		Dextromethorphan Hydrobromide	5 mg in 5 mL	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)		Guaifenesin	100 mg in 5 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
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				
Color	RED	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-946-03	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	

