

MUCINEX CHILDRENS COUGH AND CONGESTION- dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride suspension

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 & Congestion

Drug Facts

Active ingredients (in each 5 mL)	Purposes
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 2.5 mg	Nasal decongestant

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
 - nasal congestion due to a cold
 - stuffy nose

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- 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 to under 12 years of age	10 mL every 4 hours
children 4 to under 6 years of age	5 mL every 4 hours
children under 4 years of age	do not use

Other information

- each 5 mL contains: **sodium 3 mg**
- store at 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 - 201 mL Bottle Carton

VALUE SIZE

Pediatrician Recommended^f

NDC 63824-947-11

**Mucinex®
Children's**

**COUGH &
CONGESTION**

**Dextromethorphan HBr 5 mg - Cough Suppressant
Guaifenesin 100 mg - Expectorant
Phenylephrine HCl 2.5 mg - Nasal Decongestant**

- ✓ **Relieves Chest Congestion**
- ✓ **Breaks up Mucus**
- ✓ **Relieves Stuffy Nose**
- ✓ **Controls Cough**

Ages

**4+
yrs**

**Very Berry
Flavor Liquid**

6.8 FL OZ (201 mL)

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



COUGH & CONGESTION

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*as an OTC brand in the Children's Cough/Cold category (AlphalmpactRxProVoice Survey)

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Also look for



CHEST CONGESTION

mini-melts™



Great-tasting chest-congestion relief in fun-to-take, convenient granule packets!

Keep carton for full information.

6.8 FL OZ (201 mL)

Ages 4+ yrs

Very Berry Flavor Liquid



LOT CODE:

EXP. DATE:

3091844



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COUGH & CONGESTION

Each dose of Very Berry flavored
Mucinex Children's
Cough & Congestion Liquid:

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



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 England
021119 3091844



HEALTH ▾ HYGIENE ▾ HOME

- stuffy nose

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-947
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 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)	
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	RED	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-947-11	1 in 1 CARTON	03/30/2018	
1		201 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	03/30/2018	

Labeler - RB Health (US) LLC (081049410)