MUCUS RELIEF CHILDRENS- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution TOPCO ASSOCIATES LLC

TopCare 44-057

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg Guaifenesin 100 mg Phenylephrine HCl 2.5 mg

Purpose

Cough suppressant Expectorant 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
- nasal congestion due to a cold
- the intensity of coughing
- stuffy nose
- the impulse to cough to help the 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

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

- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

When using this product

do not exceed recommended dosage.

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 persists more than 7 days, tends to recur, or is accompanied by a 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 take more than directed
- do not take more than 6 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- dose as follows or as directed by a doctor

Age	Dose
children 6 to under 12 years	10 mL every 4 hours
children 4 to under 6 years	5 mL every 4 hours
children under 4 years	do not use

Other information

- each 5 mL contains: sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

anhydrous citric acid, FD&C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol, sucralose, xanthan gum

Questions or comments?

1-888-423-0139

Principal display panel

TopCare®

health

NDC 76162-057-88

COMPARE TO MUCINEX®
CHILDREN'S MULTI-SYMPTOM COLD
ACTIVE INGREDIENTS*

children's

Multi-Symptom Cold

Mucus

Relief

DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT **GUAIFENESIN -** EXPECTORANT **PHENYLEPHRINE HCI -** NASAL DECONGESTANT

ORAL SOLUTION

- Controls Cough
- Relieves Chest Congestion
- Breaks Up Mucus
- Relieves Stuffy Nose

Ages 4

to

11 Years

BERRY

FLAVOR

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Mucinex® Children's Multi-Symptom Cold. 50844 ORG022305788



MUCUS RELIEF CHILDRENS

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-057

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	
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)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162- 057-88	1 in 1 CARTON	03/07/2024	
1		201 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/07/2024	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		967626305	manufacture(76162-057) , pack(76162-057)	

Revised: 3/2024 TOPCO ASSOCIATES LLC