

TOPCARE CHILDRENS MUCUS RELIEF MULTI SYMPTOM COLD- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Topco Associates 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.

Topco Associates LLC. Children's Mucus Relief Multi-Symptom Cold Drug Facts

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

Phenylephrine HCl 2.5 mg

Purposes

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
- 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

- your child gets nervous, dizzy or sleepless
- 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 (1-800-222-1222).

Directions

- do not take 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
- mL = milliliter

Age	Dose
children 6 years to under 12 years	10 mL every 4 hours
children 4 years 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
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

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

children's

Multi-Symptom

Cold

Mucus Relief

OUR PHARMACISTS RECOMMEND

COUGH SUPPRESSANT – DEXTROMETHORPHAN HBr

EXPECTORANT - GUAIFENESIN

NASAL DECONGESTANT – PHENYLEPHRINE HCl

Controls Cough

Relieves Chest Congestion

Breaks Up Mucus

Relieves Stuffy Nose

ALCOHOL FREE

Ages 4 to 12 Years

VERY BERRY FLAVOR

4 FL OZ (118mL)



TOPCARE CHILDRENS MUCUS RELIEF MULTI SYMPTOM COLD			
dextromethorphan hbr, guaifenesin, phenylephrine hcl solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-839
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED (clear)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-839-26	1 in 1 CARTON	08/08/2014	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/08/2014	

Labeler - Topco Associates LLC (006935977)