MUCUS RELIEF SEVERE CONGESTION AND COUGH- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution TOPCO ASSOCIATES LLC

TopCare 44-004

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg Guaifenesin 400 mg Phenylephrine HCl 10 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
 - the intensity of coughing
 - the impulse to cough to help you get to sleep
 - nasal congestion due to a cold

Warnings

Do not use

• if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- heart disease
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- diabetes
- thyroid disease

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.

If pregnant or breast-feeding,

ask a health professional before use.

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
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

Other information

- each 20 mL contains: sodium 9 mg
- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose, xanthan gum

Questions or comments?

1-800-426-9391

Principal Display Panel

+TopCare®

health

NDC 76162-040-45

COMPARE TO MUCINEX® FAST-MAX® SEVERE CONGESTION & COUGH ACTIVE INGREDIENTS*

MAXIMUM STRENGTH

Mucus Relief Severe Congestion & Cough

DEXTROMETHORPHAN HBr COUGH SUPPRESSANT GUAIFENESIN • EXPECTORANT PHENYLEPHRINE HCI • NASAL DECONGESTANT

MULTI-SYMPTOM RELIEF:

- Controls Cough
- Relieves Nasal &

Chest Congestion

Thins & Loosens

Mucus

FOR AGES 12+

6 FL OZ (177 mL)

Mixed Berry Flavored

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

PARENTS:

Learn about teen medicine abuse www.StopMedicineAbuse.org

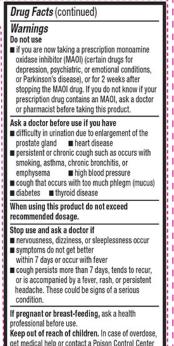
DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007 ©TOPCO LNKA0223 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com

Visit here or call 1-888-423-0139 for more information: http://topbrnds.com/4902b6

*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Mucinex® FAST-MAX® Severe Congestion & Cough. 50844 ORG042300445







■ 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 adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours ■ children under 12 years: do not use Other information ■ each 20 mL contains: sodium 9 mg ■ use by expiration date on package ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) Inactive ingredients anhydrous citric acid, FD&C blue #1, FD&C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose, xanthan gum Questions or comments? 1-888-423-0139 This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Mucinex® FAST-MAX® Severe Congestion & Cough.

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Drug Facts (continued)

Directions

Reep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center

TopCare 44-004 ORG0423

MUCUS RELIEF SEVERE CONGESTION AND COUGH

dextromethorphan hbr, quaifenesin, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-040
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
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)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	blue	Score	
Shape		Size	
Flavor	BERRY (MIXED)	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:76162- 040-45	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/10/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/10/2023	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		967626305	manufacture(76162-040), pack(76162-040)	

Revised: 8/2023 TOPCO ASSOCIATES LLC