MUCUS RELIEF COLD, FLU AND SORE THROAT- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution TOPCO ASSOCIATES LLC

TopCare 44-005

Active ingredients (in each 20 mL)

Acetaminophen 650 mg Dextromethorphan HBr 20 mg Guaifenesin 400 mg Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - sinus congestion and pressure
 - stuffy nose
 - cough
 - headache
 - nasal congestion
 - sore throat
- temporarily promotes nasal and/or sinus drainage
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash

skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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
- 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 10 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

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

Questions or comments?

1-888-423-0139

Principal Display Panel

+TopCare®

health

NDC 76162-050-45 COMPARE TO MAXIMUM STRENGTH MUCINEX® FAST-MAX® COLD, FLU & SORE THROAT ACTIVE INGREDIENTS*

MAXIMUM STRENGTH Mucus Relief Cold, Flu & Sore Throat

ACETAMINOPHEN
PAIN RELIEVER • FEVER REDUCER
DEXTROMETHORPHAN HBr • COUGH SUPPRESSANT
GUAIFENESIN • EXPECTORANT
PHENYLEPHRINE HCI • NASAL DECONGESTANT

MULTI-SYMPTOM RELIEF:

- Relieves Body Pain & Headache
- Controls Cough
- Relieves Nasal &

Chest Congestion

• Thins & Loosens

Mucus

FOR AGES 12+ 6 FL OZ (177 mL) Mixed Berry Flavored

©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/4902b5

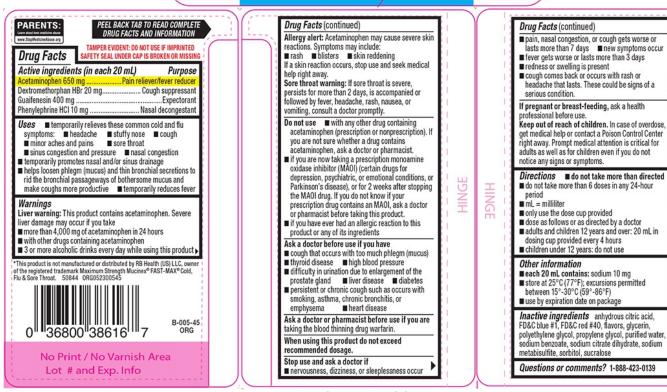
QUALITY GUARANTEED

PARENTS:

Learn about teen medicine abuse www.StopMedicineAbuse.org

*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX® Cold, Flu & Sore Throat. 50844 ORG052300545





TopCare 44-005

MUCUS RELIEF COLD. FLU AND SORE THROAT

acetaminophen, dextromethorphan hbr, quaifenesin, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-050
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL	
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)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
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)				

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
		NDC:76162- 050-45	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/11/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/11/2023	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		967626305	manufacture(76162-050) , pack(76162-050)	

Revised: 8/2023 TOPCO ASSOCIATES LLC