#### MUCINEX FAST-MAX COLD, FLU AND SORE THROAT MAXIMUM STRENGTHacetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled 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.

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Mucinex® Fast-Max<sup>®</sup> Cold, Flu and Sore Throat Maximum Strength

#### **Drug Facts**

Active ingredients (in each liquid gel)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- temporarily relieves these common cold and flu symptoms:
  - nasal congestion
  - headache
  - cough
  - minor aches and pains
  - sore throat
- 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 12 liquid gels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

#### Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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.

#### Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

## Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

#### When using this product do not use more than directed

#### Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, 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.

#### Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick 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 (see Overdose warning)
- do not take more than 12 liquid gels in any 24-hour period
- adults and children 12 years of age and over: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

#### Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat

#### Inactive ingredients

FD&C yellow no. 6, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

#### 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

#### **PRINCIPAL DISPLAY PANEL - 16 Capsule Blister Pack Carton**

Fast Dissolving Liquid Gels!

NDC 72854-127-16

MAXIMUM STRENGTH

Mucinex® FAST-MAX®

COLD, FLU & SORE THROAT

Acetaminophen – Pain Reliever/Fever Reducer Dextromethorphan HBr – Cough Suppressant Guaifenesin – Expectorant Phenylephrine HCl – Nasal Decongestant

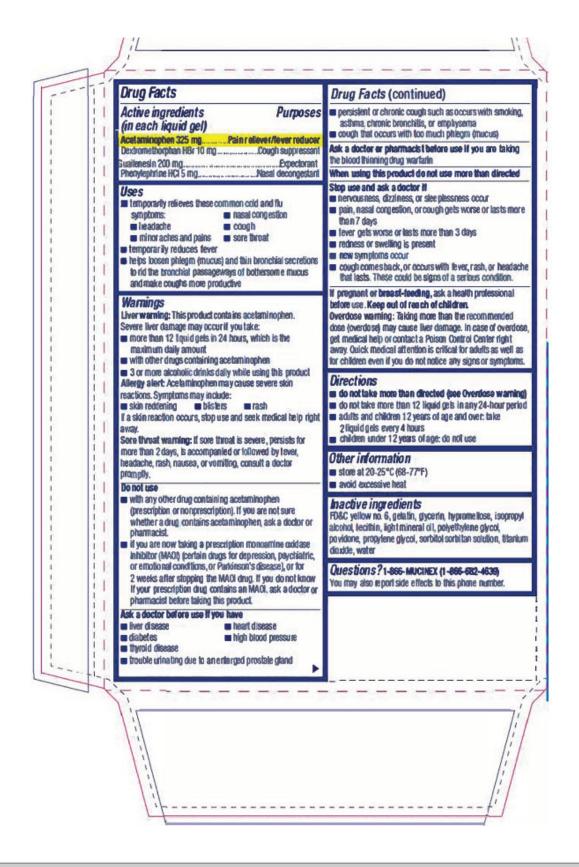
✓ Controls Cough, Thins & Loosens Mucus
✓ Relieves Nasal & Chest Congestion
✓ Relieves Headache
✓ Reduces Fever

16 LIQUID GELS (Liquid Filled Capsules)

Actual Size

DAY TIME FOR AGES 12+





# MUCINEX FAST-MAX COLD, FLU AND SORE THROAT MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled

**Product Information** 

HUMAN OTC DRUG

Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
FD&C yellow no. 6 (UNII: H77VEI93A8)				
gelatin, unspecified (UNII: 2G86QN327L)				
glycerin (UNII: PDC6A3C0OX)				
hypromellose, unspecified (UNII: 3NXW29V3WO)				
isopropyl alcohol (UNII: ND2M416302)				
light mineral oil (UNII: N6K5787QVP)				
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)				
povidone, unspecified (UNII: FZ989GH94E)				
propylene glycol (UNII: 6DC9Q167V3)				
titanium dioxide (UNII: 15FIX9V2JP)				
water (UNII: 059QF0KO0R)				

Color	ORANGE	Score	no score
Shape	OVAL	Size	24mm
Flavor		Imprint Code	AR01
Contains			

Pac		-
1100	100	
Par		
IUU		
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#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-127- 16	2 in 1 CARTON	07/26/2021	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
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### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC MONOGRAPH	part341	07/26/2021	

## Labeler - RB Health (US) LLC (081049410)

Revised: 7/2021

RB Health (US) LLC