# MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, coated 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 ® Severe Congestion and Cough Drug Facts

Active ingredients (in each caplet)	Purposes
Dextromethorphan HBr 10 mg	Cough
Dextrometrior priari fibrility	suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCI 5 mg	Nasal
Phenylephinile rici 5 mg	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

- 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)

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

### 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 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.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

#### Other information

store at 20-25°C (68-77°F)

#### **Inactive ingredients**

croscarmellose sodium, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, methacrylic acid-ethyl acrylate copolymer, mica, microcrystalline cellulose, polyethylene glycol 3350, polysorbate 80, polyvinyl alcohol, povidone K29/32, sodium bicarbonate, talc, titanium dioxide

#### 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 - 20 Caplet Blister Pack Carton

MAXIMUM STRENGTH NDC 63824-193-21

Mucinex® FAST-MAX®

SEVERE CONGESTION & COUGH

Dextromethorphan HBr - Cough Suppressant

Guaifenesin – Expectorant Phenylephrine HCl – Nasal Decongestant

- ✓ Controls Cough
- ✓ Relieves Nasal & Chest Congestion
- ✓ Thins & Loosens Mucus

**Actual Size** 

20 CAPLETS FOR AGES 12+ MAXIMUM STRENGTH



Tamper evident: Do not use if carton is damaged; or if printed seal on blister is broken or missing.

# SEVERE CONGESTION & COUGH

MAXIMUM STRENGTH



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FOR AGES 12+

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#### **Drug Facts**

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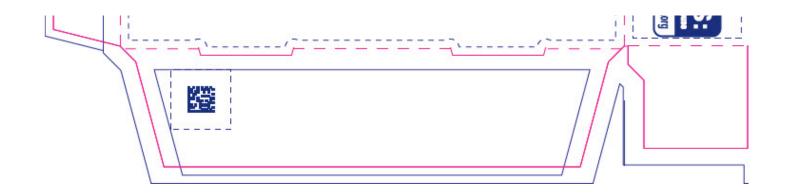
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### **MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH**

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-193		
Route of Administration	ORAL				

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

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MICA (UNII: V8A1AW0880)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
POVIDONE K30 (UNII: U725QWY32X)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics			
Color	red	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	VVV;SCC

#### **Contains**

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824- 193-20	2 in 1 CARTON	03/15/2013	05/27/2024
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824- 193-30	3 in 1 CARTON	03/15/2013	09/01/2025
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63824- 193-21	2 in 1 CARTON	10/01/2020	
3		10 in 1 BLISTER PACK; 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	03/15/2013	

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

Revised: 8/2023 RB Health (US) LLC