

**MUCINEX FAST-MAX CONGESTION AND HEADACHE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, film 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®  
Congestion & Headache**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purposes</b>
<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - nasal congestion
  - fever
  - headache
  - minor aches and pains
  - sinus congestion and pressure
- temporarily promotes nasal and/or sinus drainage
- 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 caplets 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.

**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 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 between 20-25°C (68-77°F)

### **Inactive ingredients**

corn starch, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

### **Questions?**

#### **1-866-MUCINEX (1-866-682-4639)**

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224

### **PRINCIPAL DISPLAY PANEL - 20 Caplet Blister Pack Carton**

MAXIMUM STRENGTH  
NDC 63824-791-01

Mucinex®  
FAST-MAX®

CONGESTION &  
HEADACHE

Acetaminophen  Pain Reliever/Fever Reducer

Guaifenesin - Expectorant

Phenylephrine HCl - Nasal Decongestant

- Relieves Headache & Fever
- Relieves Nasal & Chest Congestion
- Thins & Loosens Mucus

20 CAPLETS  
FOR AGES 12+

**MAXIMUM STRENGTH**

NDC 63824-791-01

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## FAST-MAX<sup>®</sup>

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Guaifenesin – Expectorant  
Phenylephrine HCl – Nasal Decongestant

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- ✓ Relieves Nasal & Chest Congestion
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**20**

**CAPLETS**

FOR AGES 12+



8335591

060718

[www.mucinex.com](http://www.mucinex.com)

**5**



**Maximum Strength  
per 4-hour dose**

**Keep outer package for  
full information.**

**Questions?**

1-866-MUCINEX (1-866-682-4639)

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LIFT HERE TO OPEN



Tamper evident: Do not use if outer package is opened or if blister is torn or broken.

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Guaifenesin 200 mg.....Expectorant  
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**Drug Facts (continued)**

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Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224 ©2018 RB

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**MUCINEX FAST-MAX CONGESTION AND HEADACHE**

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, film coated

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63824-791

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	SCP
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-791-01	2 in 1 CARTON	08/01/2018	09/01/2025
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part341	08/01/2018	09/01/2025

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

Revised: 9/2023

RB Health (US) LLC