

**MUCINEX FAST-MAX NIGHT TIME COLD AND FLU- acetaminophen, diphenhydramine hydrochloride, 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.*

-----

**Mucinex® Fast-Max®**

**Night Time Cold & Flu**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purposes</b>
<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
- cough
- minor aches and pains
- headache
- nasal congestion
- sore throat
- sinus congestion and pressure
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever
- controls cough to help you get to sleep
- temporarily reduces fever

**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.

### **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.
- with any other product containing diphenhydramine, even one used on the skin
- 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, 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
- taking sedatives or tranquilizers

### **When using this product**

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

### **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 at 20-25°C (68-77°F)

### **Inactive ingredients**

croscarmellose sodium, crospovidone, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, ferric oxide yellow, methacrylic acid - ethyl acrylate copolymer (1:1) type A, mica, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, 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  
Made in England

### **PRINCIPAL DISPLAY PANEL - 8 Caplet Pouch Carton**

NDC 63824-793-08

MAXIMUM STRENGTH

Mucinex®

FAST-MAX<sup>®</sup>

NIGHT TIME COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Diphenhydramine HCl – Antihistamine/Cough Suppressant

Phenylephrine HCl – Nasal Decongestant

HEADACHE

SORE THROAT

ITCHY THROAT

BODY PAIN

FEVER

COUGH

ALL IN

ONE\*

NASAL CONGESTION

SNEEZING

RUNNY NOSE

8 CAPLETS

(4 Pouches: 2 Caplets each)

FOR AGES 12+



**RB Artwork and Print Specification**

Product Reference No:	RB3050
ZBU Ref:	TR1519732
Action:	<b>B</b>
Brand:	Mucinex
Category:	A&H
Segment Group:	FastMax
Segment:	All-in-One Night Time Cold & Flu
Peak Size:	4 Pak
Market/Country:	USA
Date:	12/07/19

RBI Contact:	Anthony Escotto
Artwork Type:	<b>IDM Commercial</b>
Component Code (S):	8357054
Parent Technical Packaging:	
Specification:	83029134
Finished Goods Code:	63824-96328-00
Steady State:	3PL USA & Canada
3rd Party Code:	N/A
Pharmaceutical No/RE:	N/A
Edgemark Position:	N/A

CAD Cam Ref:	Muc-Ca-000P12-3372676P135r
Printer:	Color One Color One (Black, N): USGA
Substrate:	Carton Board - White

Color	Color 2 of applicable
Grayscale	Grayscale 2 of applicable

Color	Color Name	Color Value	Color Value
Yellow	Yellow	CMYK	RGB
Cyan	Cyan	CMYK	RGB
Magenta	Magenta	CMYK	RGB
Black	Black	CMYK	RGB

**BARCODE INFO**

Barcode Type:	UPC 12
Barcode Number:	8 357054 330
Magnification:	100%
Printed By:	4 4 mm
Bar Height:	23.1 mm
Bar Height (Smallest Bar):	18.0 mm
Spine:	28 mm
Enabled Date:	N/A



Please note that any low-resolution paper color values associated with this job should be referred to for content, layout and color separation only.

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

STUDIO USE ONLY: Amanda Lewis v2.0  
 Studio Address: (P) 0-111-1111, (A) 011-111-1111

MIN PT SIZE & HEIGHT (Non-Automatic)	
NET WT (in 8 FL OZ 150ml)	30x36 50pt
Drug Facts Size	30x36 50pt
Active Ingredient Table	30x36 50pt
Active Ingredient (SDP) Ingredient	30x36 50pt
File Size of Other Copy	30x36 50pt

**CUSTOMER INFO:**  
 Minimum Point Size = 1.00pt

**MUCINEX FAST-MAX NIGHT TIME COLD AND FLU**  
 acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, film coated

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-793
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>MICA</b> (UNII: V8A1AW0880)	
<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>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	VV;CF
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-793-08	4 in 1 CARTON	09/10/2018	
1	NDC:63824-793-02	2 in 1 POUCH; 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	09/10/2018	

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