

**MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated**  
**RB Health (US) LLC**

-----  
**Mucinex® Fast-Max®**

**Cold & Flu**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purposes</i></b>
<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
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
  - sinus congestion and pressure
- 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 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.
- 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 at 20-25°C (68-77°F)

### **Inactive ingredients**

croscarmellose sodium, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, 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**

NDC 63824-575-21

MAXIMUM STRENGTH

Mucinex®

FAST-MAX®

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Guaifenesin – Expectorant

Phenylephrine HCl – Nasal Decongestant

SORE THROAT

FEVER

CHEST CONGESTION

COUGH

NASAL CONGESTION

SINUS CONGESTION

SINUS PRESSURE

HEADACHE

BODY PAIN

ALL IN

ONE\*

Actual Size

20 CAPLETS

FOR AGES 12+





**20 CAPLETS**

Actual Size  
  
 FOR AGES 12+

Dist. by: RB Health (US)  
 Parsippany, NJ 07054-0224  
 ©2020 RB Health  
 040820 3141640  
  
 3 63824 19220 8

LOT:  
 EXP.:  
 MADE IN:  
 3141640



**Drug Facts**  
**Active ingredients (in each caplet) Purposes**  
 Acetaminophen 325 mg ..... Pain reliever/fever reducer  
 Dextromethorphan HBr 10 mg ..... Cough suppressant  
 Guaifenesin 200 mg ..... Expectorant  
 Pseudoephedrine HCl 5 mg ..... Nasal decongestant

**Uses**  
 ■ temporarily relieves these common cold and flu symptoms:  
 ■ nasal congestion ■ headache ■ cough  
 ■ minor aches and pains ■ sore throat  
 ■ sinus congestion and pressure  
 ■ 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 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

**Drug Facts (continued)**  
 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

**Mucinex**  
**FAST-MAX**  
 MAXIMUM STRENGTH  
**COLD & FLU**

**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) ▶

■ 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 red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide

**Questions? 1-866-MUCINEX (1-866-682-4639)**  
 You may also report side effects to this phone number.

Maximum Strength per 4-hr dose  
 \*helps to relieve these symptoms day or night  
 Do not take more than a total of 12 caplets in any 24-hour period.  
 Take only as directed.  
 Keepcaplet for full information.

**PARENTS:**  
 Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



## MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-575
<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>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 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>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<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>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	MSC;VW
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-575-20	2 in 1 CARTON	07/28/2018	05/03/2024
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-575-44	4 in 1 CARTON	07/28/2018	
2	NDC:63824-575-72	2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:63824-575-21	2 in 1 CARTON	09/01/2020	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:63824-575-10	1 in 1 CARTON	07/12/2021	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:63824-575-04	1 in 1 CARTON	07/28/2018	
5		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 Drug M012

07/28/2018

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

Revised: 11/2023

RB Health (US) LLC