

**MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU AND MUCINEX NIGHTSHIFT SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride**  
**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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**Maximum Strength Mucinex® Fast-Max® Cold & Flu and Mucinex® NightShift Severe Cold & Flu**

**Drug Facts**

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<b>Active ingredients (in each 20 mL)</b>	<b>Purposes</b>
<b>MUCINEX FAST-MAX COLD &amp; FLU</b>	
<b>Acetaminophen 650 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

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<b>Active ingredients (in each 20 mL)</b>	<b>Purposes</b>
<b>MUCINEX NIGHTSHIFT SEVERE COLD &amp; FLU</b>	
<b>Acetaminophen 650 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant
Triprolidine HCl 2.5 mg	Antihistamine

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**Uses**

**MUCINEX FAST-MAX COLD & FLU**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - stuffy nose
  - 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

### **MUCINEX NIGHTSHIFT SEVERE COLD & FLU**

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

### **Warnings**

#### **Liver warning**

This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 4000 mg 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
- glaucoma (***Nightshift Severe Cold & Flu only***)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (***Nightshift Severe Cold & Flu only***)
- 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
- taking sedatives or tranquilizers (***Nightshift Severe Cold & Flu only***)

### **When using this product**

- **do not use more than directed**
- excitability may occur, especially in children (***Nightshift Severe Cold & Flu only***)
- marked drowsiness may occur (***Nightshift Severe Cold & Flu only***)
- alcohol, sedatives, and tranquilizers may increase drowsiness (***Nightshift Severe Cold & Flu only***)
- avoid alcoholic drinks (***Nightshift Severe Cold & Flu only***)
- use caution when driving a motor vehicle or operating machinery (***Nightshift Severe Cold & Flu only***)

### **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

### **MUCINEX FAST-MAX COLD & FLU**

- **do not take more than directed (see Overdose warning)**
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

### **MUCINEX NIGHTSHIFT SEVERE COLD & FLU**

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

## Other information

- each 20 mL contains: **sodium 12 mg (Fast-Max Cold & Flu only)** and **sodium 16 mg (Nightshift Severe Cold & Flu only)**
- store at 20-25°C (68-77°F)
- do not refrigerate

## Inactive ingredients (MUCINEX FAST-MAX COLD & FLU)

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate <sup>1</sup>, xanthan gum

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<sup>1</sup> may contain this ingredient

## Inactive ingredients (MUCINEX NIGHTSHIFT SEVERE COLD & FLU)

ammonium glycyrrhizate, anhydrous citric acid, ascorbic acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, triacetin, triethyl citrate, water, xanthan gum

## 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 - Kit Carton**

NDC 63824-505-26

DAY & NIGHT COLD & FLU PACK

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

HEADACHE

BODY PAIN

ALL IN

ONE\*

CHEST CONGESTION

COUGH

NASAL CONGESTION

SINUS CONGESTION

SINUS PRESSURE

FOR

AGES 12+

TWO - 6 FL OZ (180 mL) bottles

MAXIMUM STRENGTH

Mucinex®

NIGHTSHIFT

SEVERE COLD & FLU

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Phenylephrine HCl - Nasal Decongestant • Triprolidine HCl - Antihistamine

SORE THROAT

FEVER

HEADACHE

BODY PAIN

ALL IN

ONE\*

ITCHY THROAT

COUGH

NASAL CONGESTION

SNEEZING

RUNNY NOSE

TOTAL - 12 FL OZ (360 mL)

FOR

AGES 12+

**Drug Facts** (continued)

**Inactive ingredients**  
(MUCINEX NIGHTSHIFT SEVERE COLD & FLU)  
ammonium glycyrrhizate, anhydrous citric acid, ascorbic acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, triacetin, triethyl citrate, water, xanthan gum

**Maximum Strength per 4-hour dose**

**Tamper evident:** Do not use if neckband on bottle cap is broken or missing.

\*FAST-MAX COLD & FLU helps to relieve these symptoms day or night; NIGHTSHIFT SEVERE COLD & FLU helps to relieve these symptoms at night

Do not take Mucinex Fast-Max Cold & Flu and Mucinex Nightshift Severe Cold & Flu at the same time. Always wait at least 4 hours before taking another dose of Mucinex liquid.  
**TAKE ONLY AS DIRECTED.**

**PARENTS:**

Learn about teen medicine abuse

www.StopMedicineAbuse.org

NDC 63824-505-26

**DAY & NIGHT COLD & FLU PACK**

**MAXIMUM STRENGTH**



**COLD & FLU**

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



**MAXIMUM STRENGTH**



**SEVERE COLD & FLU**

**Acetaminophen** – Pain Reliever/Fever Reducer  
**Dextromethorphan HBr** – Cough Suppressant  
**Phenylephrine HCl** – Nasal Decongestant • **Triprolidine HCl** – Antihistamine



**FOR AGES 12+ TWO – 6 FLOZ (180 mL) bottles TOTAL – 12 FL OZ (360 mL) FOR AGES 12+**

No coating

Made in England Dist. by: RB Health (US), Parsippany, NJ 07054-0224 ©2020 RB Health

**Drug Facts** (continued)

**Active ingredients (in each 20 mL) Purposes**  
**MUCINEX NIGHTSHIFT SEVERE COLD & FLU**  
Acetaminophen 650 mg ..... Pain reliever/fever reducer  
Dextromethorphan HBr 20 mg ..... Cough suppressant  
Phenylephrine HCl 10 mg ..... Nasal decongestant  
Triprolidine HCl 2.5 mg ..... Antihistamine

**Drug Facts** (continued)

**Warnings:** This product contains acetaminophen (prescription or over-the-counter). It may contain a narcotic (prescription or over-the-counter).  
Severe liver damage may occur if you take:  
■ more than 4000 mg in 24 hours, which is the maximum daily amount  
■ with other drugs containing acetaminophen  
■ 3 or more alcoholic drinks daily while using this product  
**Other information**  
■ Ask a doctor before use if you have liver disease, diabetes, glaucoma (Nightshift Severe Cold & Flu only), thyroid disease, or trouble urinating due to an enlarged prostate gland (Nightshift Severe Cold & Flu only)  
■ 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  
■ Excitability may occur, especially in children (Nightshift Severe Cold & Flu only)

**Drug Facts**

**Active ingredients (in each 20 mL) Purposes**  
**MUCINEX FAST-MAX COLD & FLU**  
Acetaminophen 650 mg ..... Pain reliever/fever reducer  
Dextromethorphan HBr 20 mg ..... Cough suppressant  
Guaifenesin 400 mg ..... Expectorant  
Phenylephrine HCl 10 mg ..... Nasal decongestant

**Drug Facts** (continued)

**Warnings:** This product contains acetaminophen (prescription or over-the-counter). It may contain a narcotic (prescription or over-the-counter).  
Severe liver damage may occur if you take:  
■ more than 4000 mg in 24 hours, which is the maximum daily amount  
■ with other drugs containing acetaminophen  
■ 3 or more alcoholic drinks daily while using this product  
**Other information**  
■ Ask a doctor before use if you have liver disease, diabetes, glaucoma (Nightshift Severe Cold & Flu only), thyroid disease, or trouble urinating due to an enlarged prostate gland (Nightshift Severe Cold & Flu only)  
■ 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  
■ Excitability may occur, especially in children (Nightshift Severe Cold & Flu only)





## MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU AND MUCINEX NIGHTSHIFT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-505
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-505-26	1 in 1 CARTON	05/30/2022	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	180 mL
Part 2	1 BOTTLE	180 mL

### Part 1 of 2

## MUCINEX NIGHTSHIFT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution

### Product Information

<b>Item Code (Source)</b>	NDC:63824-504
<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	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL



<b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL
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## Inactive Ingredients

Ingredient Name	Strength
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-504-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/01/2020	

## Part 2 of 2

### MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

## Product Information

**Item Code (Source)** NDC:63824-548

**Route of Administration** ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYL GALLATE</b> (UNII: 8D45NN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-548-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/28/2018	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/19/2020	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Reckitt Benckiser (UK) Ltd.		227363660	manufacture(63824-505)

### Establishment

Name	Address	ID/FEI	Business Operations
Reckitt Benckiser LLC		111829557	label(63824-505)

Revised: 6/2023

RB Health (US) LLC