

**MUCINEX FAST-MAX COLD, FLU AND SORE THROAT AND MUCINEX NIGHTSHIFT COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride**  
**RB Health (US) LLC**

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**Mucinex® Fast-Max® Cold, Flu & Sore Throat and Mucinex® NightShift Cold & Flu**

***Drug Facts***

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***Active ingredients (in each 20 mL)***

***Mucinex Fast-Max Cold, Flu & Sore Throat*** ***Purposes***

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<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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***Active ingredients (in each 20 mL)***

***Mucinex Nightshift Cold & Flu*** ***Purposes***

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<b>Acetaminophen 650 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 20 mg	Cough suppressant
Triprolidine HCl 2.5 mg	Antihistamine

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**Uses**

**MUCINEX FAST-MAX COLD, FLU & SORE THROAT**

- 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
- 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

## **MUCINEX NIGHTSHIFT COLD & FLU**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
  - 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 (**Fast-Max Cold, Flu & Sore Throat only**)

- diabetes (**Fast-Max Cold, Flu & Sore Throat only**)
- high blood pressure (**Fast-Max Cold, Flu & Sore Throat only**)
- thyroid disease (**Fast-Max Cold, Flu & Sore Throat only**)
- glaucoma (**Nightshift Cold & Flu only**)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (**Nightshift 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 Cold & Flu only**)

**When using this product**

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

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur (**Fast-Max Cold, Flu & Sore Throat only**)
- pain, nasal congestion, or cough gets worse or lasts more than 7 days (**Fast-Max Cold, Flu & Sore Throat only**)
- pain or cough gets worse or lasts more than 7 days (**Nightshift Cold & Flu only**)
- 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 & SORE THROAT**

- **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 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 & Sore Throat only)** and **sodium 16 mg (Nightshift Cold & Flu only)**
- store at 20-25°C (68-77°F)
- do not refrigerate

## **Inactive ingredients (Mucinex Fast-Max Cold, Flu & Sore Throat)**

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), 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 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**

DAY & NIGHT  
COLD & FLU RELIEF

MAXIMUM STRENGTH

NDC 63824-119-66

Mucinex®  
FAST-MAX®

COLD, FLU  
& SORE THROAT

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

- Controls Cough, Thins & Loosens Mucus
- Nasal & Chest Congestion
- Sinus Pressure & Congestion
- Body Pain, Headache, Fever & Sore Throat

Mucinex®  
NIGHTSHIFT

COLD & FLU

Acetaminophen - Pain Reliever/Fever Reducer  
Dextromethorphan HBr - Cough Suppressant  
Triprolidine HCl - Antihistamine

NIGHTTIME  
RELIEF FOR A BETTER  
MORNING

✓COUGH ✓FEVER ✓SORE THROAT  
✓RUNNY NOSE ✓SNEEZING

FOR  
AGES 12+

TWO - 6 FL OZ (180 mL) bottles  
TOTAL - 12 FL OZ (360 mL)

FOR  
AGES 12+

**Drug Facts** (continued)

**Other information**

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

**Inactive ingredients (Mucinex Fast-Max Cold, Flu & Sore Throat)**

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), propyl galate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate\*, xanthan gum  
\*may contain this ingredient

**Inactive ingredients (Mucinex Nightshift 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

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

**DAY & NIGHT COLD & FLU RELIEF**

MAXIMUM STRENGTH

NDC 63824-119-66



**COLD, FLU & SORE THROAT**

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

- ✓ Controls Cough, Thins & Loosens Mucus
- ✓ Nasal & Chest Congestion
- ✓ Sinus Pressure & Congestion
- ✓ Body Pain, Headache, Fever & Sore Throat



**COLD & FLU**

**Acetaminophen** – Pain Reliever/Fever Reducer  
**Dextromethorphan HBr** – Cough Suppressant  
**Tripolidine HCl** – Antihistamine



- ✓ COUGH ✓ FEVER ✓ SORE THROAT
- ✓ RUNNY NOSE ✓ SNEEZING

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

**No coating**

Dist. by: RB Health (US), Parsippany, NJ 07054-0224 Tamper evident: Do not use if neckband on bottle cap is broken or missing.

**Drug Facts** (continued)

**Active ingredients (in each 20 mL) Purposes**

**Mucinex Nightshift Cold & Flu**  
 Acetaminophen 650 mg.....Pain reliever/fever reducer  
 Dextromethorphan HBr 20 mg.....Cough suppressant  
 Tripolidine HCl 2.5 mg.....Antihistamine

**Drug Facts**

**Active ingredients (in each 20 mL) Purposes**

**Mucinex Fast-Max Cold, Flu & Sore Throat**  
 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)

- 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 Cold & Flu only)

When using this product: ■ do not use more than directed

■ excitability may occur, especially in children (Nightshift Cold & Flu only)

■ marked drowsiness may occur (Nightshift Cold & Flu only)

■ alcohol, sedatives, and tranquilizers may increase drowsiness (Nightshift Cold & Flu only)

■ a valid alcoholic drinks (Nightshift Cold & Flu only)

■ use caution when driving a motor vehicle or operating machinery (Nightshift Cold & Flu only)

Stop use and ask a doctor if:

■ nervousness, dizziness, or sleeplessness occur (Fast-Max Cold, Flu & Sore Throat only)

■ pain, nasal congestion, or cough gets worse or lasts more than 7 days (Fast-Max Cold, Flu & Sore Throat only)

■ pain or cough gets worse or lasts more than 7 days (Nightshift Cold & Flu only)

■ 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. This could be the 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 & SORE THROAT**  
 ■ 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

**Drug Facts** (continued)

**Uses**

**MUCINEX FAST-MAX COLD, FLU & SORE THROAT**  
 ■ 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

■ 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

**MUCINEX NIGHTSHIFT COLD & FLU**

■ temporarily relieves these common cold and flu symptoms:  
 ■ cough ■ minor aches and pains ■ sore throat ■ headache ■ runny nose ■ sneezing

■ itching of the nose or throat

■ itchy, watery eyes due to hay fever

■ temporarily reduces fever

■ contracts 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 redness ■ blisters ■ rash

■ a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 7 days, is accompanied or followed by fever, headache, rash, reusua, 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 (Fast-Max Cold, Flu & Sore Throat only)



HEALTH • HYGIENE • HOME  
 Questions? 1-866-MUCINEX

**PARENTS:**





# MUCINEX FAST-MAX COLD, FLU AND SORE THROAT AND MUCINEX NIGHTSHIFT 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:63824-119
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-119-66	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	06/30/2022	04/01/2025

## 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 COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride solution

## Product Information

<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	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
<b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL

## Inactive Ingredients

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

## Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-503-66	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 Drug	M012	06/15/2019	

## Part 2 of 2

### MUCINEX FAST-MAX COLD, FLU AND SORE THROAT

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

## Product Information

Route of Administration	ORAL
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## 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>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<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:63824-015-66	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 Drug	M012	02/07/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/17/2019	04/01/2025

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

Revised: 11/2023

RB Health (US) LLC