MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH AND MUCINEX NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride RB Health (US) LLC

## Mucinex® Fast-Max ® Severe Congestion & Cough and Mucinex® Nightshift Cold & Flu

## **Drug Facts**

Dextromethorphan HBr 20 mg......Cough suppressant Guaifenesin 400 mg......Expectorant Phenylephrine HCl 10mg. . . . . . . . . . . . . . Nasal decongestant Acetaminophen 650mg......Pain reliever/fever reducer Dextromethorphan HBr 20 mg.....Cough suppressant Phenylephrine HCl 10 mg. . . . . . . . . . . . Nasal decongestant 

Active ingredients (in each 20 mL) **Purposes** Mucinex Fast-Max Severe Congestion & Cough Dextromethorphan HBr 20 mg Cough suppressant Guaifenesin 400 mg **Expectorant** Phenylephrine HCl 10 mg Nasal decongestant

Active ingredients (in each 20 mL) Mucinex Nightshift Cold & Flu

**Purposes** 

Acetaminophen 650 mg

Pain reliever/fever reducer

Dextromethorphan HBr 20 mg Cough suppressant Triprolidine HCl 2.5 mg

**Antihistamine** 

#### Uses

Mucinex Fast-Max Severe Congestion & Cough

■ helps loosen phlegm (mucus) and thin bronchial secretions to rid

the bronchial passageways of bothersome mucus and make

coughs more productive

■ temporarily relieves:

- cough due to minor throat and bronchial irritation as may
- occur with the common cold or inhaled irritants
- the intensity of coughing nasal congestion due to a cold
- temporarily helps you cough less

## Mucinex Nighttime Cold & Flu

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

### **MUCINEX FAST-MAX SEVERE CONGESTION & COUGH**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - nasal congestion due to a cold
  - the impulse to cough to help you get to sleep

### **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 (Nighttime Cold & Flu only): 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 (Nighttime Cold & Flu only):

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 (Nighttime Cold & Flu only): 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.

# Liver warning (Nightshift Cold & Flu only)

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 (Nightshift Cold & Flu only)

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 (Nightshift Cold & Flu only)

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. (Nightshift Cold & Flu only)
- 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 (Nightshift Cold & Flu only)
- heart disease (Fast-Max Severe Congestion & Cough only)
- high blood pressure (Fast-Max Severe Congestion & Cough only)
- thyroid disease (Fast-Max Severe Congestion & Cough only)
- diabetes (Fast-Max Severe Congestion & Cough 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 (Nightshift Cold & Flu only)
- 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

- pain or cough gets worse or lasts more than 7 days (Nightshift Cold & Flu only)
- fever gets worse or lasts more than 3 days (Nightshift Cold & Flu only)
- redness or swelling is present (Nightshift Cold & Flu only)
- new symptoms occur (Nightshift Cold & Flu only)
- cough comes back or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. (Nightshift Cold & Flu only)
- nervousness, dizziness, or sleeplessness occur (Fast-Max Severe Congestion & Cough only)
- symptoms do not get better within 7 days or occur with fever (Fast-Max Severe Congestion & Cough only)
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache

that lasts. These could be signs of a serious condition. (Fast-Max Severe Congestion & Cough only)

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## Overdose warning (Nightshift Cold & Flu only)

Taking more than the recommended dose (overdose) may cause liver damage. 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 Severe Congestion & Cough

Clear & Cool

- 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 Nighttime 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

### **MUCINEX FAST-MAX SEVERE CONGESTION & COUGH**

- 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

9 mg (Fast-Max Severe

Congestion & Cough only) and sodium 16 mg

(Nighttime Cold & Flu I only)

- store at 20-25°C (68-77°F)
- do not refrigerate

# Inactive ingredients (Mucinex Fast-Max Severe Congestion & Cough)

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

# Inactive ingredients (Mucinex Nighttime Cold & Flu)

ammonium glycyrrhizate, anhydrous citric acid, edetate disodium, FD&C blueno.1, FD&Credno.40, flavor, glycerin (soy), propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, 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** 

**COUGH & COLD RELIEF** 

MAXIMUM STRENGTH

NDC 72854-166-26

Mucinex®

FAST-MAX ®

SEVERE CONGESTION

& COUGH

Dextromethorphan HBr - Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCl - Nasal Decongestant

- Controls Cough
- Relieves Nasal & Chest Congestion
- Thins & Loosens Mucus

Mucinex ®

**NIGHTTIME** 

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+** 



### When using this product do not use more than directed

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and franquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

#### Stop use and ask a doctor if

- pain 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.

children under 12 years of age: do not use

#### Other information

- each 20 mL contains: sodium 12 mg
- store at 20-25°C (68-77°F)
- do not refrigerate

#### Inactive ingredients

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

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

# MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH AND MUCINEX NIGHTTIME COLD AND FLU

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

#### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:72854-166

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1	NDC:72854-166-26	1 in 1 CARTON	06/01/2025			

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

<b>Product Information</b>	
Item Code (Source)	NDC:63824-503
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL		
TRIPROLIDINE HYDROCHLORIDE (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)			

Product Characteristics				
Color blue Score				
Shape		Size		
Flavor	FRUIT	Imprint Code		
Contains				

ı	Packaging				
	# Item Package Description		Marketing Start Date	Marketing End Date	
	1		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 SEVERE CONGESTION AND COUGH**

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information	
Item Code (Source)	NDC:63824-540
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL		

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		

FD&C RED NO. 40 (UNII: WZB9127XOA)

PROPYL GALLATE (UNII: 8D4SNN7V92)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

SODIUM BENZOATE (UNII: OJ245FE5EU)

SORBITOL (UNII: 506T60A25R)

SUCRALOSE (UNII: 96K6UQ3Z D4)

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)

XANTHAN GUM (UNII: TTV12P4NEE)

Product Characteristics				
Color	red	Score		
Shape		Size		
Flavor	FRUIT	Imprint Code		
Contains				

ı	P	Packaging							
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
	1		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	01/11/2017			

Marketing In	Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M012	06/01/2025				

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

Revised: 7/2025 RB Health (US) LLC