

**MUCINEX FAST-MAX COLD AND FLU ARCTIC BURST AND NIGHTSHIFT SEVERE COLD AND FLU ARCTIC BURST- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, triprolidine hydrochloride**  
**RB Health (US) LLC**

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**Mucinex® Fast-Max Cold & Flu Arctic Burst and Nightshift Severe Cold & Flu Arctic Burst**

***Drug Facts***

<b><i>Active ingredients (in each 20 mL)</i></b>	<b><i>Purposes</i></b>
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10mg	Nasal decongestant
ACETAMINOPHEN 650 mg	Pain Reliever

<b><i>Active ingredients (in each 20 mL)</i></b>	<b><i>Purposes</i></b>
<b>Acetaminophen 650 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant
Tripolidine HCl 2.5 mg	Antihistamine

**Uses**

**Mucinex Fast-Max**

- 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 Nightshift**

- 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

## Warnings

### Liver warning (Nightshift 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 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 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 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 only)**
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma **(Nightshift only)**
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis **(Nightshift 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 Clear & Cool only**)
- taking sedatives or tranquilizers (**Nightshift Cold & Flu Clear & Cool only**)

**When using this product**

- **do not use more than directed**
- excitability may occur, especially in children (**Nightshift Cold & Flu Clear & Cool only**)
- marked drowsiness may occur (**Nightshift Cold & Flu Clear & Cool only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nightshift Cold & Flu Clear & Cool only**)
- avoid alcoholic drinks (**Nightshift Cold & Flu Clear & Cool only**)
- use caution when driving a motor vehicle or operating machinery (**Nightshift Cold & Flu Clear & Cool 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 (**Nightshift Cold & Flu Clear & Cool only**)
- fever gets worse or lasts more than 3 days (**Nightshift Cold & Flu Clear & Cool only**)
- redness or swelling is present (**Nightshift Cold & Flu Clear & Cool only**)
- new symptoms occur (**Nightshift Cold & Flu Clear & Cool only**)
- symptoms do not get better within 7 days or occur with fever (**Fast-Max Severe Congestion & Cough Clear & Cool only**)
- 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.**In case of overdose, get medical help or contact a Poison Control Center right away.

**Overdose warning (Nightshift Cold & Flu Clear & Cool 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 Nightshift Cold & Flu Clear & Cool**

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

### **Inactive ingredients**

#### **(Mucinex Fast-Max Severe Congestion & Cough Clear & Cool)**

anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin, propyl gallate, propylene glycol, sodium benzoate, sodium citrate, sorbitol, sucralose, water, xanthan gum

#### **(Mucinex Nightshift Cold & Flu Clear & Cool)**

ammonium glycyrrhizate, anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, 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**

MAXIMUM STRENGTH

NDC 63824-135-26

Mucinex®  
FAST-MAX®

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCl - Nasal Decongestant

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

FOR

AGES 12+

TWO - 6 FL OZ (180 mL) bottles

Mucinex®  
NIGHTSHIFT

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Phenylephrine HCl - Nasal Decongestant

Triprolidine HCl - Antihistamine

NIGHTTIME

RELIEF FOR A BETTER

MORNING

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

TOTAL - 12 FL OZ (360 mL)

FOR

AGES 12+

MAXIMUM STRENGTH

# Mucinex®

## FAST-MAX®

### COLD & FLU ARCTIC BURST™

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



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

NDC 72854-135-26

# Mucinex®

## NIGHTSHIFT™

### SEVERE COLD & FLU ARCTIC BURST™

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



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

**TOTAL – 12 FL OZ (360 mL)** FOR AGES 12+

**Drug Facts** (continued)

**Other information**

- each 20 mL contains:  
sodium 9 mg (Fast-Max  
Cold & Flu Arctic Burst  
only) and sodium 16 mg  
(Nightshift Severe Cold &  
Flu Arctic Burst only)
- store at 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients**  
(MUCINEX FAST-MAX COLD  
& FLU ARCTIC BURST)

anhydrous citric acid, D&C  
yellow no. 10, edetate  
disodium, FD&C blue no. 1,  
flavors, glycerin, propyl gallate,  
propylene glycol, sodium  
benzoate, sodium citrate,  
sorbitol, sucralose, water,  
xanthan gum

**Inactive ingredients**  
(MUCINEX NIGHTSHIFT SEVERE  
COLD & FLU ARCTIC BURST)

ammonium glycyrrhizate,  
anhydrous citric acid, D&C  
yellow no. 10, edetate disodium,  
FD&C blue no. 1, flavors,  
glycerin (soy), propylene glycol,  
sodium benzoate, sorbitol,  
sucralose, water, xanthan gum

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

Made in England

### Drug Facts

#### Active ingredients (in each 20 mL) Purposes **MUCINEX FAST-MAX COLD & FLU ARCTIC BURST**

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)

#### Active ingredients (in each 20 mL) Purposes **MUCINEX NIGHTSHIFT SEVERE COLD & FLU ARCTIC BURST**

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)

#### Uses **MUCINEX FAST-MAX COLD & FLU ARCTIC BURST**

- 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

#### Uses **MUCINEX NIGHTSHIFT SEVERE COLD & FLU ARCTIC BURST**

- 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 4,000 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 Arctic Burst only**)
  - trouble urinating due to an enlarged prostate gland
  - a breathing problem such as emphysema or chronic bronchitis (**Nightshift Severe Cold & Flu Arctic Burst only**)
  - persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
  - cough that occurs with too much phlegm (mucus) ▶

### Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers  
(**Nightshift Severe Cold & Flu Arctic Burst only**)

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

- excitability may occur, especially in children (**Nightshift Severe Cold & Flu Arctic Burst only**)
- marked drowsiness may occur (**Nightshift Severe Cold & Flu Arctic Burst only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nightshift Severe Cold & Flu Arctic Burst only**)
- avoid alcoholic drinks (**Nightshift Severe Cold & Flu Arctic Burst only**)
- use caution when driving a motor vehicle or operating machinery (**Nightshift Severe Cold & Flu Arctic Burst 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.**

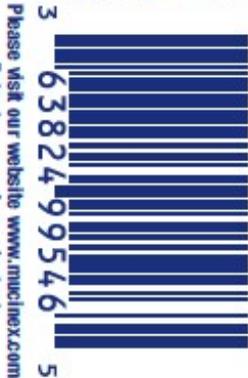
**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions

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

- 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 ARCTIC BURST**
- 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 ▼

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



HEALTH • HYGIENE • HOME

**Questions?** 1-866-MUCINEX (1-866-682-4639)  
You may also report side effects to the phone number: 1-800-FDA-1088  
**FAST-MAX COLD & FLU ARCTIC BURST** helps to relieve these symptoms day or night.

## MUCINEX FAST-MAX COLD AND FLU ARCTIC BURST AND NIGHTSHIFT SEVERE COLD AND FLU ARCTIC BURST

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

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72854-135

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-135-26	1 in 1 PACKAGE, COMBINATION	06/01/2021	05/15/2023

## 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 ARCTIC BURST

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

## Product Information

Item Code (Source)	NDC:72854-250
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

XANTHAN GUM (UNII: TTV12P4NEE)

### Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-250-66	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	07/01/2021	

## Part 2 of 2

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

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

### Product Information

Item Code (Source)	NDC:72854-133
Route of Administration	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (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:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-133-66	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	07/01/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2021	05/15/2025

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