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

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**Mucinex® Nightshift™ Severe Cold & Flu Arctic Burst™**

***Drug Facts***

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

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
  - sinus congestion and pressure
  - 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
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, 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

**When using this product**

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

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal decongestion, 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 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 16 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

### Inactive ingredients

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 - 180 mL Bottle Label

COOLING
MENTHOL
FLAVOR

3186232
021021

NDC 72854-250-66

Mucinex®
NIGHTSHIFT™

SEVERE COLD & FLU

ARCTIC BURST™

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

6 FL OZ (180 mL)

FOR AGES 12+

022221
3186242


NDC 72854-250-66

3186242

022221

# Mucinex®

## NIGHTSHIFT™

## SEVERE COLD & FLU

## ARCTIC BURST™

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PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

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

Maximum Strength per 4-hour dose

**PARENTS:**
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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Please visit our website
www.mucinex.com

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
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031119

LOT: 3094781 EXP: MADE IN:

flu symptoms:

- cough
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- sneezing
- sinus congestion and pressure
- itching of the nose or throat
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PEEL HERE

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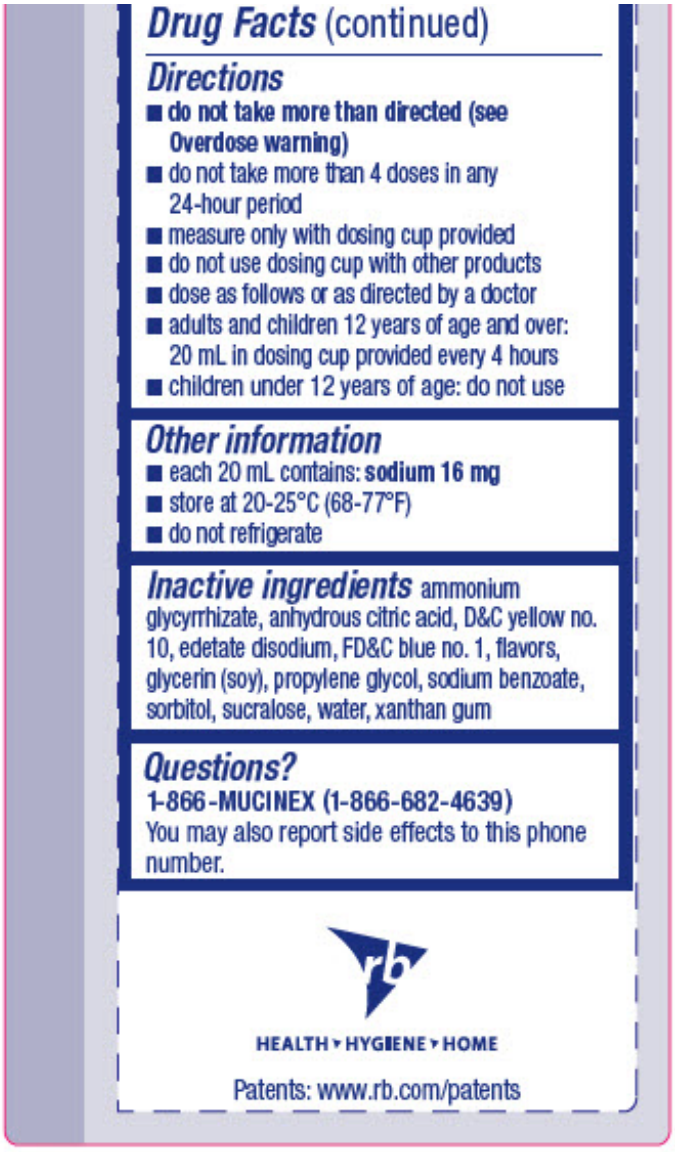


# MUCINEX NIGHTSHIFT SEVERE COLD AND FLU ARCTIC BURST

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

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **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:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 20 mL |
| **TRIPROLIDINE HYDROCHLORIDE** (UNII: YAN7R5L890) (TRIPROLIDINE - | TRIPROLIDINE | 2.5 mg |

| | | |
|---|---|---|
| UNII:2L8T9S52QM) | HYDROCHLORIDE | 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) | 07/01/2021 | 05/15/2025 |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 07/01/2021 | 05/15/2025 |

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

Revised: 11/2023 RB Health (US) LLC