

**MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH AND MUCINEX NIGHTSHIFT 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.*

**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  
 Triprolidine HCl 2.5 mg. . . . . Antihistamine

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| <b>Active ingredients (in each 20 mL)</b>             |                    | <b>Purposes</b> |
|---|--------------------|-----------------|
| <b>Mucinex Fast-Max Severe Congestion &amp; Cough</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 Cold &amp; Flu</b>  |                                    |                 |
| <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 Severe Congestion & Cough Clear & Cool
- 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 Cold & Flu Clear & Cool

- 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 (Nightshift Cold & Flu Clear & Cool 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 Clear & Cool 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 Clear & Cool 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 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

## **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 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)**

anhydrous citric acid, edetate disodium, 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  
COUGH & COLD RELIEF

MAXIMUM STRENGTH  
NDC 63824-117-66

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®  
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 Severe Congestion & Cough 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 Severe Congestion & Cough)**

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, spodium 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 Severe Congestion & Cough 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  
COUGH & COLD RELIEF**

**MAXIMUM STRENGTH**

NDC 63824-117-66



**SEVERE CONGESTION  
& COUGH**

Dextromethorphan HBr – Cough Suppressant  
Guaifenesin – Expectorant  
Phenylephrine HCl – Nasal Decongestant

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



**COLD & FLU**

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



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

FOR AGES 12+ **TWO – 6 FLOZ (180 mL) bottles** TOTAL – 12 FLOZ (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  
Triprolidine HCl 2.5 mg.....Antihistamine

**Drug Facts**  
**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

**Drug Facts** (continued)  
**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  
■ do not use more than 7 days (Nightshift Cold & Flu only)  
■ 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 (Nightshift Cold & Flu only)  
■ 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)

**Drug Facts** (continued)  
**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  
■ 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  
■ 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 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  
**Alert (Nightshift Cold & Flu only):** Acetaminophen may cause severe skin reactions. Symptoms may include:  
■ skin redness  
■ 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)  
■ 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)

**Directions**  
**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 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 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)  
■ 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)





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Please visit our website [www.mucinex.com](http://www.mucinex.com)  
 Patents: [www.rb.com/patents](http://www.rb.com/patents)  
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Questions?  
 1-866-MUCINEX  
 (1-866-682-4639)  
 You may also report  
 side effects to this  
 phone number.  
 Maximum Strength per 4-hour dose

**PARENTS:**  
 Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

## MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH 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:63824-117 |
|---------------------|----------------|---------------------------|---------------|

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:63824-117-66 | 1 in 1 CARTON       | 06/30/2022           |                    |

### 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 COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride solution

### Product Information

|                                |               |
|--------------------------------|---------------|
| <b>Item Code (Source)</b>      | NDC:63824-503 |
| <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<br>in 20 mL |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 20 mg<br>in 20 mL  |
| <b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)        | TRIPROLIDINE<br>HYDROCHLORIDE    | 2.5 mg<br>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 final | part341                                  | 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   | Basis of Strength                | Strength           |
|---|----------------------------------|--------------------|
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH)<br>(DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 20 mg<br>in 20 mL  |
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                           | GUAIFENESIN                      | 400 mg<br>in 20 mL |
| <b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)         | PHENYLEPHRINE<br>HYDROCHLORIDE   | 10 mg<br>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 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>    | red   | <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:63824-540-66 | 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                                  | 01/11/2017           |                    |

### Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part341   | 06/24/2019                  |                           |

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

Revised: 6/2023

RB Health (US) LLC