**MUCINEX FAST-MAX COLD AND FLU ARCTIC BURST MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution**
**RB Health (US) LLC**

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**Mucinex® Fast-Max ®Cold & Flu Arctic Burst™**
**Maximum Strength**

***Drug Facts***

| ***Active ingredients (in each 20 mL)*** | ***Purposes*** |
|---|---|
| **Acetaminophen 650 mg** | **Pain reliever/fever reducer** |
| Dextromethorphan HBr 20 mg | Cough suppressant |
| Guaifenesin 400 mg | Expectorant |
| Phenylephrine HCl 10 mg | Nasal decongestant |

**Uses**

- 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

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 doses 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
- trouble urinating due to an enlarged prostate gland
- 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

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

**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**

- **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

**Other information**

- each 20 mL contains: **sodium 9 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

**Inactive ingredients**

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

**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
Made in England

**PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label**

NDC 72854-133-66

MAXIMUM STRENGTH
Mucinex®
FAST-MAX ®

COLD & FLU
ARCTIC BURST™

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

HEADACHE
SORE THROAT
CHEST CONGESTION

BODY PAIN
FEVER
COUGH

ALL IN
ONE*

NASAL CONGESTION

SINUS CONGESTION
SINUS PRESSURE

6 FL OZ (180 mL)
FOR AGES 12 +

022221
3186229

NDC 72854-133-66

MAXIMUM STRENGTH

# Mucinex®

## FAST-MAX®

3186229

022221

## COLD & FLU

## ARCTIC BURST™

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


**6 FL OZ (180 mL)**

**FOR AGES 12+**

**PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION**

Maximum Strength per 4-hour dose
Tamper evident: Do not use if neckband on bottle cap is broken or missing.
*Helps to relieve these symptoms day or night

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

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## Drug Facts (continued)

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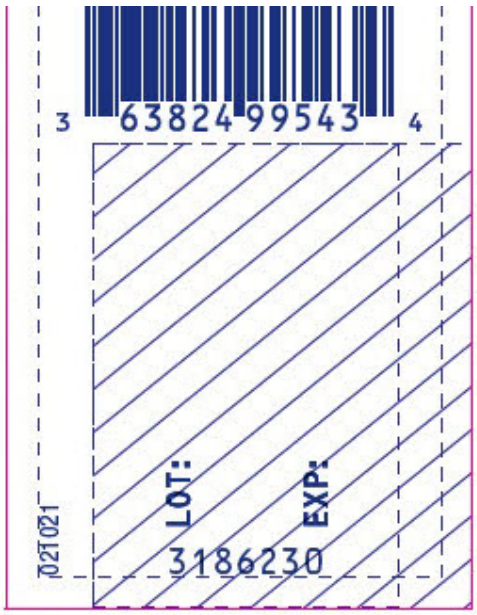


## Uses

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## Drug Facts (continued)

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## Drug Facts (continued)

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## Drug Facts (continued)

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### Other information

- each 20 mL contains: **sodium 9 mg**
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### Inactive ingredients

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## Drug Facts (continued)

### Questions?

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COOLING MENTHOL FLAVOR



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

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **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** |

| | |
|---|---|
| **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) | |
| **PROPYL GALLATE** (UNII: 8D4SNN7V92) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | green | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | MENTHOL | **Imprint Code** | |
| **Contains** | | | |

## 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) | 07/01/2021 | 09/10/2024 |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 07/01/2021 | 09/10/2024 |

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

Revised: 11/2023 RB Health (US) LLC