MUCINEX FAST-MAX CONGESTION AND HEADACHE- acetaminophen, guaifenesin, and phenylephrine hydrochloride solution RB Health (US) LLC

Mucinex® Fast-Max ® Congestion & Headache

Drug Facts

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

Uses

- temporarily relieves these common cold and flu symptoms:
 - nasal congestion
 - headache
 - minor aches and pains
 - sinus congestion and pressure
- temporarily reduces fever
- temporarily promotes nasal and/or sinus drainage
- 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.

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 12 mg**
- store between 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate ¹, xanthan gum

1 may contain this ingredient

Questions?

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

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label MAXIMUM STRENGTH*

NDC 63824-536-66

060616 3036245

Mucinex® FAST-MAX®

CONGESTION & HEADACHE

Acetaminophen- Pain Reliever/Fever Reducer Guaifenesin - Expectorant Phenylephrine HCl - Nasal Decongestant

- ✓ Relieves Headache & Fever
- ✓ Relieves Nasal & Chest Congestion
- ✓ Thins & Loosens Mucus

6 FL OZ (180mL)

FOR AGES 12+



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Mucinex

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Drug Facts (continued)

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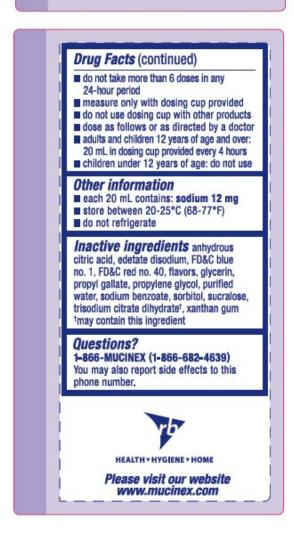
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MUCINEX FAST-MAX CONGESTION AND HEADACHE

acetaminophen, guaifenesin, and phenylephrine hydrochloride solution

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63824-536 | |
| Route of Administration | ORAL | | | |

| Active Ingredient/Active Moiety | | | |
|---|--------------------------------|--------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) | ACETAMINOPHEN | 650 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) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYL GALLATE (UNII: 8D4SNN7V92) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| | |

| Product Characteristics | | | |
|-------------------------|------|--------------|--|
| Color | blue | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| 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) | 10/01/2016 | 04/01/2025 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 10/01/2016 | 04/01/2025 |
| | | | |

Labeler - RB Health (US) LLC (081049410)

Revised: 10/2023 RB Health (US) LLC