MUCINEX FAST-MAX COLD, FLU AND SORE THROAT- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution
RB Health (US) LLC
Reference Label Set Id: 1c540456-8a20-4ba9-a6b2-c0f5fc4ec3b5

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®
Cold, Flu & Sore Throat

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
- 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 sever skin reactions. Symptoms may include:
- skin reddening
- blister
- 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 thining 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 older: 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 8 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

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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 63824-015-66

Mucinex®
FAST-*MAX®*

COLD, FLU

& SORE THROAT

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

- ✓ **Controls Cough, Thins & Loosens Mucus**
- ✓ **Nasal & Chest Congestion**
- ✓ **Sinus Pressure & Congestion**
- ✓ **Body Pain, Headache, Fever & Sore Throat**

6 FL OZ (180 mL)
FOR AGES 12+

071817
3051674

MAXIMUM STRENGTH*

NDC 63824-015-66

071817 3051674

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PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

*Per 4-hour dose

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

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

3 63824 01565 1

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Dist. by: Reckitt Benckiser
Parsippany, NJ 07054-0224
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082317

LOT: 3051679
EXP:
MADE IN:

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Drug Facts (continued)

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.

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PEEL HERE

Drug Facts (continued)

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Drug Facts (continued)

Other information

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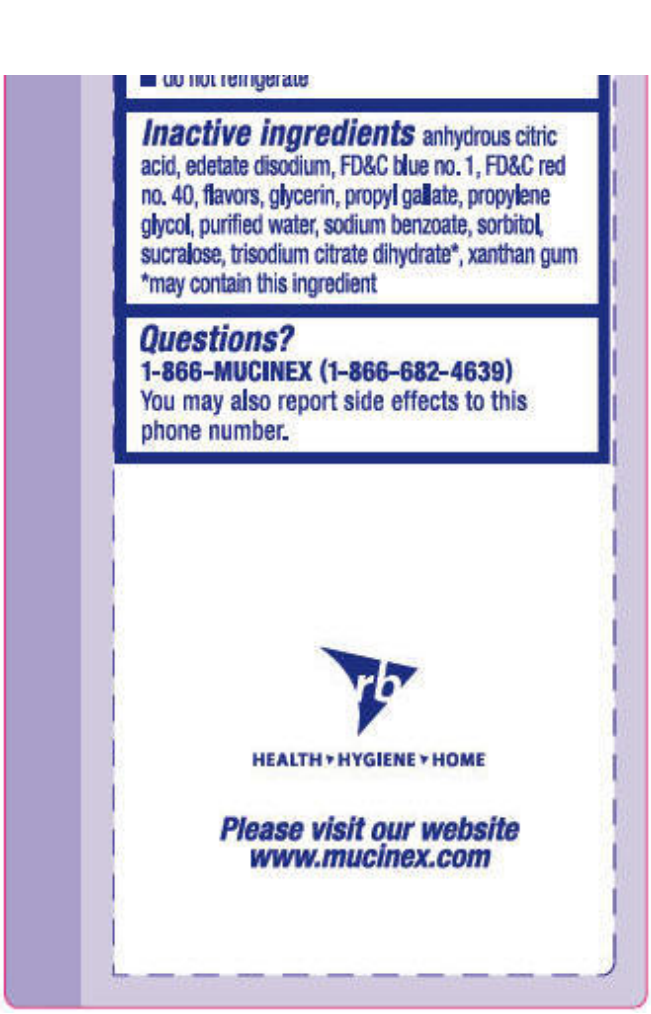
9 SYMPTOM



MUCINEX FAST-MAX COLD, FLU AND SORE THROAT

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-015
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)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
FD&C Red NO. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
propyl gallate (UNII: 8D4SNN7V92)	
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	FRUIT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-015-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	02/07/2012	
2	NDC:63824-015-69	266 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	02/07/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/07/2012	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022 RB Health (US) LLC