

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

Maximum Strength Mucinex® Fast-Max® Cold & Flu

Drug Facts

<i>Active ingredients (in each 20 mL)</i>	<i>Purposes</i>
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 12 mg**
- store at 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 (soy), 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: RB Health (US)
Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 63824-548-64

MAXIMUM STRENGTH

Mucinex®

FAST-MAX®

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Guaifenesin – Expectorant

Phenylephrine HCl - Nasal Decongestant

HEADACHE

BODY PAIN

SORE THROAT

FEVER

CHEST CONGESTION

COUGH

ALL IN

ONE*

NASAL CONGESTION

SINUS CONGESTION

SINUS PRESSURE

4 FL OZ (118 mL)

FOR AGES 12+

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

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FAST-MAX

COLD & FLU

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Drug Facts (continued)

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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 at 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 (soy), propyl gallate, propylene glycol, purified water,
sodium benzoate, sorbitol, sucralose, trisodium citrate
dihydrate*, xanthan gum *may contain this ingredient

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

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4 FL OZ (118 mL) FOR AGES 12+



LOT CODE:

EXP. DATE:

MADE IN:

3097114

Pharma
Code

Keep carton for full information.

Maximum Strength per 4-hour dose

*Helps to relieve these symptoms
day or night

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Drug Facts

Active ingredients (in each 20 mL)

Purposes

Acetaminophen 650 mg.....	Pain reliever/fever reducer
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Phenylephrine HCl 10 mg.....	Nasal decongestant

Uses

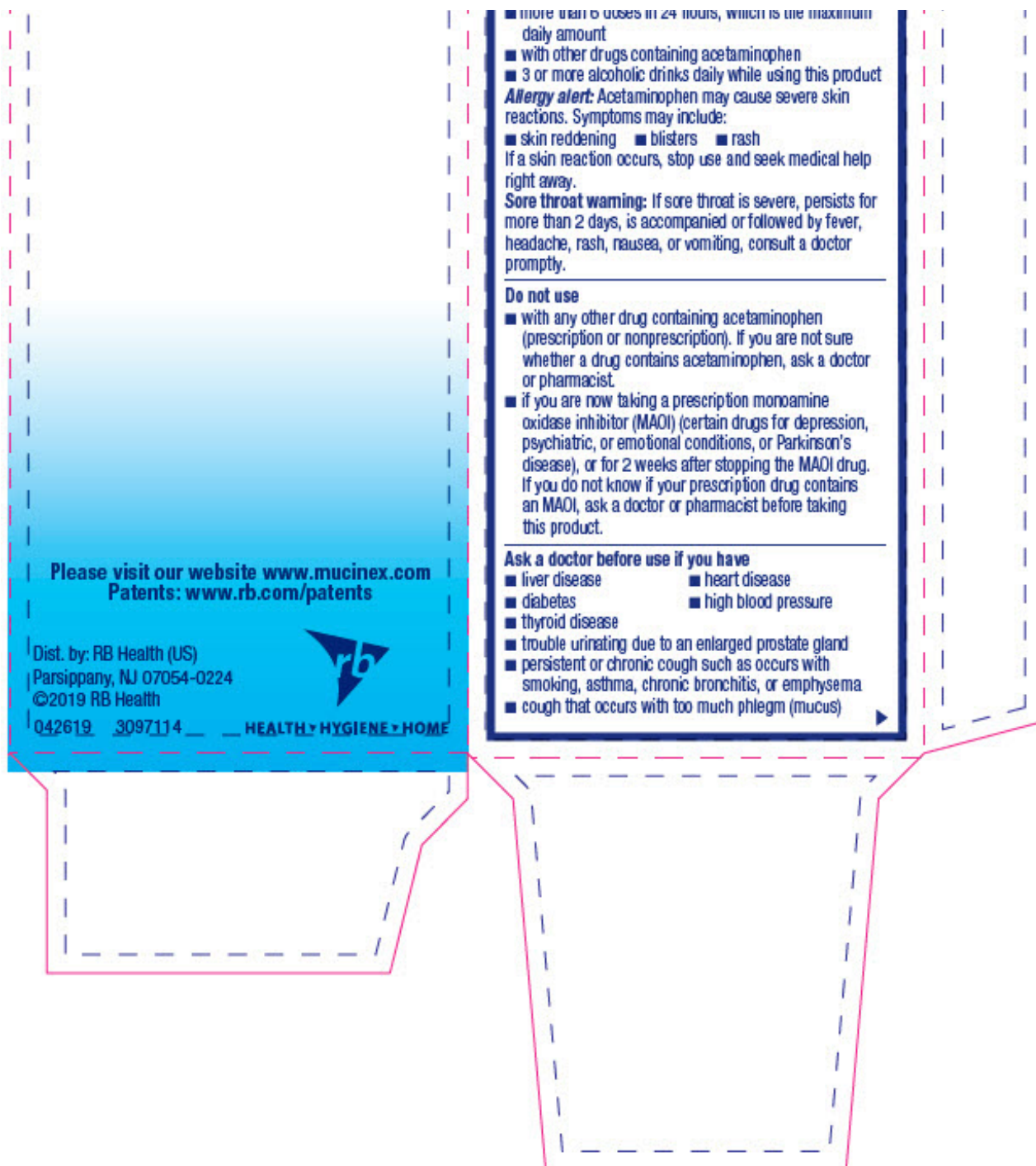
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Warnings

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— more than 2 doses in 24 hours, which is the maximum



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acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-548
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)	
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	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-548-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	07/28/2018	
2	NDC:63824-548-69	266 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	07/28/2018	
3	NDC:63824-548-64	1 in 1 CARTON	10/01/2018	
3		118 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
4	NDC:63824-548-33	3 in 1 CARTON	08/01/2023	
4		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 Drug	M012	07/28/2018	

Labeler - RB Health (US) (081049410)

Revised: 5/2024

RB Health (US)