# MAXIMUM STRENGTH MUCINEX SINUS-MAX SEVERE CONGESTION AND PAINacetaminophen, guaifenesin, and phenylephrine hydrochloride solution 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.

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# Maximum Strength Mucinex® Sinus-Max® Severe Congestion and Pain

# **Drug Facts**

Active ingredients (in each 20 mL)	Purposes
Acetaminophen 650 mg	Pain reliever
Guaifenesin 400 mg	Expectorant
Dhonylanhrina UCl 10 mg	Nasal
Phenylephrine HCl 10 mg	decongestant

#### Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
- 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 MAOI, ask a doctor or pharmacist before taking this product.

# Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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<sup>1</sup>, 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 63824-266-66

Mucinex® SINUS-MAX®

# SEVERE CONGESTION & PAIN

**Acetaminophen** – Pain Reliever Guaifenesin – Expectorant Phenylephrine HCl – Nasal Decongestant

- Clears Sinus Congestion
- Relieves Headache
- Thins & Loosens Mucus

# 6 FL OZ (180 mL)

FOR AGES 12+

030817

3045443

**MAXIMUM STRENGTH\*** 

NDC 63824-266-66

817 30

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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.



# **Drug Facts**

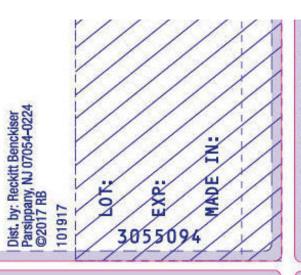
# Active ingredients (in each 20 mL)

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# Drug Facts (continued)

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## Directions

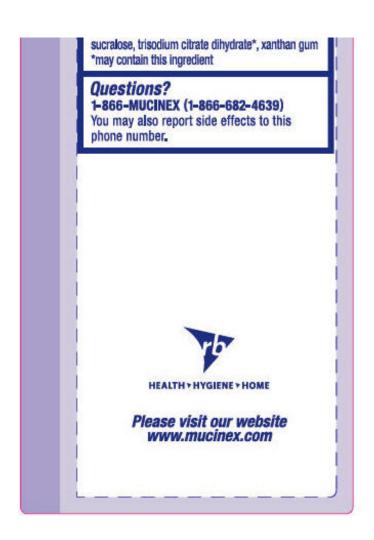
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# Drug Facts (continued)

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,



# MAXIMUM STRENGTH MUCINEX SINUS-MAX SEVERE CONGESTION AND PAIN

acetaminophen, guaifenesin, and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-266
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Acetaminophen (UNII: 36209 ITL9D) (Acetaminophen - UNII:36209 ITL9D)	Acetaminophen	650 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (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			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
			180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/01/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	0 3/0 1/20 18		

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

Revised: 2/2020 RB Health (US) LLC