## MUCINEX SINUS-MAX SEVERE CONGESTION AND PAIN MAXIMUM STRENGTHacetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled 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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# Mucinex® Sinus-Max® Severe Congestion & Pain Maximum Strength

## **Drug Facts**

Active ingredients (in each liquid gel)	Purposes	
Acetaminophen 325 mg	Pain reliever	
Dextromethorphan HBr 10 mg	Cough suppressant	
Phenylephrine HCl 5 mg	Nasal decongestant	

#### Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
  - cough
- temporarily promotes nasal and/or sinus drainage

## Warnings

## Liver warning

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

- more than 12 liquid gels 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, 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 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 12 liquid gels in any 24-hour period
- adults and children 12 years of age and over: take 2 liquid gels every 4 hours

children under 12 years of age: do not use

#### Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat

### **Inactive ingredients**

FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

#### **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 - 16 Capsule Blister Pack Carton

Fast Dissolving Liquid Gels!

NDC 72854-203-16

MAXIMUM STRENGTH

Mucinex® SINUS-MAX®

SEVERE CONGESTION & PAIN

Acetaminophen – Pain Reliever Dextromethorphan HBr – Cough Suppressant Phenylephrine HCl – Nasal Decongestant

- ✓ Clears Sinus Congestion
- ✓ Relieves Headache
- ✓ Controls Cough

#### **Actual Size**

16 LIQUID GELS (Liquid Filled Capsules)

DAY TIME FOR AGES 12+





# MUCINEX SINUS-MAX SEVERE CONGESTION AND PAIN MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72854-203

**Route of Administration** 

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
FD&C red no. 40 (UNII: WZB9127XOA)				
FD&C yellow no. 6 (UNII: H77VEI93A8)				
gelatin, unspecified (UNII: 2G86QN327L)				
glycerin (UNII: PDC6A3C0OX)				
hypromellose, unspecified (UNII: 3NXW29V3WO)				
isopropyl alcohol (UNII: ND2M416302)				
light mineral oil (UNII: N6K5787QVP)				
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)				
povidone, unspecified (UNII: FZ 989GH94E)				
propylene glycol (UNII: 6DC9Q167V3)				
titanium dioxide (UNII: 15FIX9V2JP)				
water (UNII: 059QF0KO0R)				

Product Characteristics				
Color	RED	Score	no score	
Shape	OVAL	Size	24mm	
Flavor		Imprint Code	AR04	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72854-203- 16	2 in 1 CARTON	07/26/2021		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/26/2021	

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

Revised: 7/2021 RB Health (US) LLC