# MUCINEX SINUS-MAX PRESSURE, PAIN AND COUGH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated 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® Pressure, Pain & Cough

#### **Drug Facts**

Active ingredients (in each caplet)	Purposes
Acetaminophen 325 mg	Pain reliever
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - cough
  - 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 12 caplets 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 12 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

#### Other information

store between 20-25°C (68-77°F)

# **Inactive ingredients**

corn starch, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

#### **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 - 20 Caplet Blister Pack Carton

MAXIMUM STRENGTH NDC 63824-250-01

Mucinex® SINUS-MAX® PRESSURE, PAIN & COUGH

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

- ✓ Relieves Sinus Pressure & Congestion
- ✓ Relieves Headache
- ✓ Controls Cough
- ✓ Thins & Loosens Mucus

FOR AGES 12+

20 CAPLETS

Varnings nasal congestion
minor aches and pains temporarily relieves: sinus congestion and pressure bothersome mucus and make coughs

iver warning: This product contains ace tarninophen evere liver damage may occur if you take: with other drugs containing acetaminophen more than 12 caplets in 24 hours, which is the 3 or more alcoholic drinks daily while using maximum daily amount

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Other information

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MAXIMUM STRENGTH

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liver disease high blood pressure thyroid disease

heart disease diabetes

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trouble urinating due to an enlarged prostate gland

Questions

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, chronic bronchitis, or emphyse ma

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





Maximum Strength per 4-hour dose

Tamper evident: Do not use if carton is damaged or if printed seal on blister is broken or missing.

Keep carton for full information.

MAXIMUM STRENGTH

NDC 63824-250-01

# 1ucinex SINUS-MAX®

**PRESSURE, PAIN & COUGH** 

Acetaminophen – Pain Reliever • Dextromethorphan HBr – Cough Suppressant Guaifenesin - Expectorant • Phenylephrine HCI - Nasal Decongestant

- Relieves Sinus Pressure & Congestion
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- **Controls Cough**
- Thins & Loosens Mucus

CAPLETS



FOR AGES 12+

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

www.mucinex.com 070618 8335610



Active ingredients in each caplet)

**Drug Facts** 

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professional before use. Keep out of reach of children. cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a f pregnant or breast-feeding, ask a health

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Purposes

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-250
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 ug	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
starch, corn (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C red no. 40 (UNII: WZB9127XOA)	
aluminum oxide (UNII: LMI26O6933)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
magnesium stearate (UNII: 70097M6I30)	
maltodextrin (UNII: 7CVR7L4A2D)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
polyvinyl alcohol, unspecified (UNII: 532B59J990)	
povidone, unspecified (UNII: FZ 989GH94E)	
silicon dioxide (UNII: ETJ7Z 6XBU4)	
stearic acid (UNII: 4ELV7Z65AP)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	RED	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	DCH	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63824- 250-01	2 in 1 CARTON	11/15/2018	

1	10 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	11/15/2018		

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

Revised: 1/2022 RB Health (US) LLC