# MUCINEX NIGHTSHIFT SINUS MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride tablet, 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® Nightshift Sinus**

### **Maximum Strength**

### **Drug Facts**

Active ingredients (in each caplet)	Purposes	
Acetaminophen 325 mg	Pain reliever/fever reducer	
Dextromethorphan HBr 10 mg	Cough suppressant	
Phenylephrine HCl 5 mg	Nasal decongestant	
Triprolidine HCl 1.25 mg	Antihistamine	

### Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - sinus congestion and pressure
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

### Warnings

### Liver warning

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

- more than 4,000 mg 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- 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
- taking sedatives or tranquilizers

### When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

### 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 8 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 at 20-25°C (68-77°F)

### Inactive ingredients

croscarmellose sodium, crospovidone, ferric oxide, hydroxypropyl cellulose, mica, microcrystalline cellulose, polyvinyl alcohol, polyvinyl alcohol polyethylene glycol copolymer, povidone, silicon dioxide, 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: RB Health (US) Parsippany, NJ 07054-0224

### PRINCIPAL DISPLAY PANEL - 20 Caplet Blister Pack Carton

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

NDC 72854-240-20

MAXIMUM STRENGTH Mucinex® NIGHTSHIFT

### SINUS

Acetaminophen – Pain Reliever/Fever Reducer Dextromethorphan HBr – Cough Suppressant Phenylephrine HCl – Nasal Decongestant Triprolidine HCl – Antihistamine

NIGHTTIME RELIEF FOR A BETTER MORNING

**ACTUAL SIZE** 

✓COUGH ✓FEVER ✓SORE THROAT ✓RUNNY NOSE ✓SNEEZING ✓NASAL CONGESTION

20 CAPLETS

FOR AGES 12+

FAST RELEASE MAXIMUM STRENGTH

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



SINUS

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

**MAXIMUM STRENGTH** 

NDC 72854-240-20

# Mucinex NIGHTSHI

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COUGH **FEVER** SORE THROAT **RUNNY NOSE** ✓ **SNEEZING** NASAL CONGESTION

ACTUAL SIZE

**20 CAPLETS** 

FOR AGES 12+

**FAST** RELEASE

LOT:

EXP.:

MADE IN:

3176508





MAXIMUM STRENGTH

Do not take more than a total of 8 caplets in any 24-hour period. Take only as directed. Maximum Strength per 4-hour

Keep carton for full information

www.StopMedicineAbuse.org

### **Drug Facts**

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ORAL

**Route of Administration** 

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-240	

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
CROSPOVIDONE (UNII: 2S7830E561)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ 8H6N6OH)			
MICA (UNII: V8A1AW0880)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
POLYVINYL ALCOHOL GRAFT POLYETHYLENE GLYCOL COPOLYMER (3:1; 45000 MW) (UNII: 23ZQ42JZZH)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics			
Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	VW;LOGOcres centmoonplus
Contains			

Pa	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:72854- 240-20	2 in 1 CARTON	07/01/2021	
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	07/01/2021	

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

Revised: 6/2023 RB Health (US) LLC