

**MUCINEX-SINUS MAX SEVERE CONGESTION AND PAIN CLEAR AND COOL AND MUCINEX NIGHTSHIFT SINUS CLEAR AND COOL- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, triprolidine hydrochloride  
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 Clear & Cool and Mucinex Nightshift Sinus Clear & Cool**

**Drug Facts**

Mucinex Sinus-Max

SEVERE CONGESTION & PAIN CLEAR & COOL

**Acetaminophen 650mg**.....Pain reliever

**Guaifenesin 400 mg**.....Expectorant

**Phenylephrine HCl 10mg**. . . . .Nasal decongestant

Mucinex Nightshift

Sinus Clear & Cool

**Acetaminophen 650mg**.....Pain reliever/fever reducer

**Dextromethorphan HBr 20 mg**.....Cough suppressant

**Phenylephrine HCl 10mg**. . . . .Nasal decongestant

**Triprolidine HCl 2.5 mg**. . . . .Antihistamine

**Uses**

Mucinex Sinus-Max SEVERE CONGESTION & PAIN CLEAR & COOL

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

Mucinex Nightshift Sinus Clear & Cool

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 4000 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 (Nightshift Sinus Clear & Cool only):** 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 (Nightshift Sinus Clear & Cool only)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (Nightshift Sinus Clear & Cool only)

- 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

- taking sedatives or tranquilizers (Nightshift Sinus Clear & Cool only)

**When using this product ■ do not use more than directed**

- excitability may occur, especially in children (Nightshift Sinus Clear & Cool only)

- marked drowsiness may occur (Nightshift Sinus Clear & Cool only)

- alcohol, sedatives, and tranquilizers may increase drowsiness (Nightshift Sinus Clear & Cool only)

- avoid alcoholic drinks (Nightshift Sinus Clear & Cool only)

- use caution when driving a motor vehicle or operating machinery (Nightshift Sinus Clear & Cool only)

**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**

**MUCINEX SINUS-MAX SEVERE CONGESTION & PAIN CLEAR & COOL**

- 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

**MUCINEX NIGHTSHIFT SINUS CLEAR & COOL**

■ do not take more than directed (see Overdose warning)

■ do not take more than 4 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

■ each 20 mL contains: sodium 9mg (Severe Congestion & Pain Clear & Cool only) and sodium 16mg (Nightshift Sinus Clear & Cool only)

■ store at 20-25°C (68-77°F)

■ do not refrigerate

**(Mucinex Sinus-Max Severe Congestion & Pain Clear & Cool)**

anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate\*, xanthan gum  
\*may contain this ingredient

**(Mucinex Nightshift Sinus Clear & Cool)**

ammonium glycyrrhizate, anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, water, xanthan gum

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

**Keep out of reach of children**

Acetaminophen 650mg.....Pain reliever  
Guaifenesin 400 mg.....Expectorant  
Phenylephrine HCl 10mg. . . . .Nasal decongestant  
Acetaminophen 650mg.....Pain reliever/fever reducer

Dextromethorphan HBr 20 mg.....Cough suppressant  
 Phenylephrine HCl 10mg. ....Nasal decongestant  
 Triprolidine HCl 2.5 mg. ....Antihistamine

<b>Drug Facts</b> (continued)	<b>MAXIMUM STRENGTH*</b> NDC 63824-116-66	<b>Mucinex® NIGHTSHIFT</b>
<b>Other information</b> ■ each 20 mL contains: sodium 9 mg (Severe Congestion & Pain Clear & Cool only) and sodium 16 mg (Nightshift Sinus Clear & Cool only) ■ store at 20-25°C (68-77°F) ■ do not refrigerate	<b>Mucinex® SINUS-MAX®</b>	<b>SINUS CLEAR &amp; COOL</b>
<b>Inactive ingredients (Mucinex Sinus-Max Severe Congestion &amp; Pain Clear &amp; Cool)</b> anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate*, xanthan gum *may contain this ingredient	<b>SEVERE CONGESTION &amp; PAIN</b>  <b>CLEAR &amp; COOL.</b>	<b>Acetaminophen – Pain Reliever/Fever Reducer Dextromethorphan HBr – Cough Suppressant Phenylephrine HCl – Nasal Decongestant Triprolidine HCl – Antihistamine</b>
<b>Inactive ingredients (Mucinex Nightshift Sinus Clear &amp; Cool)</b> ammonium glycyrrhizate, anhydrous citric acid, D&C yellow no. 10, edetate disodium, FD&C blue no. 1, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, water, xanthan gum	<b>Acetaminophen – Pain Reliever Guaifenesin – Expectorant Phenylephrine HCl – Nasal Decongestant</b>  ✓ <b>Clears Sinus Congestion</b> ✓ <b>Relieves Headache</b> ✓ <b>Thins &amp; Loosens Mucus</b>	<b>NIGHTTIME RELIEF FOR A BETTER MORNING</b>  ✓ <b>COUGH</b> ✓ <b>FEVER</b> ✓ <b>SORE THROAT</b> ✓ <b>RUNNY NOSE</b> ✓ <b>SNEEZING</b> ✓ <b>NASAL CONGESTION</b>
Do not take Mucinex Sinus-Max Severe Congestion & Pain Clear & Cool and Mucinex Nightshift Sinus Clear & Cool at the same time. Always wait at least 4 hours before taking another dose of Mucinex liquid. TAKE ONLY AS DIRECTED.	<b>FOR AGES 12+ TWO – 6 FL OZ (180 mL) bottles</b>	<b>TOTAL – 12 FL OZ (360 mL) FOR AGES 12+</b>

<b>Drug Facts</b>	<b>Drug Facts</b> (continued)
<b>Active ingredients (in each 20 mL) Purposes</b> <b>Mucinex Sinus-Max</b>	<b>Active ingredients (in each 20 mL) Purposes</b> <b>Mucinex Nightshift Sinus Clear &amp; Cool</b>
<b>SEVERE CONGESTION &amp; PAIN CLEAR &amp; COOL</b>	
Acetaminophen 650 mg.....Pain reliever Guaifenesin 400 mg.....Expectorant Phenylephrine HCl 10 mg.....Nasal decongestant ▶	Acetaminophen 650 mg.....Pain reliever/fever reducer Dextromethorphan HBr 20 mg.....Cough suppressant Phenylephrine HCl 10 mg.....Nasal decongestant Triprolidine HCl 2.5 mg.....Antihistamine ▼

## Drug Facts (continued)

### Uses **Mucinex Sinus-Max SEVERE CONGESTION & PAIN CLEAR & COOL**

- 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

### **Mucinex Nightshift Sinus Clear & Cool**

- 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 4000 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 (Nightshift Sinus Clear & Cool only):** 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 (**Nightshift Sinus Clear & Cool only**)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (**Nightshift Sinus Clear & Cool only**)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

## Drug Facts (continued)

- 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 (**Nightshift Sinus Clear & Cool only**)

## When using this product do not use more than directed

- excitability may occur, especially in children (**Nightshift Sinus Clear & Cool only**)
- marked drowsiness may occur (**Nightshift Sinus Clear & Cool only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Nightshift Sinus Clear & Cool only**)
- avoid alcoholic drinks (**Nightshift Sinus Clear & Cool only**)
- use caution when driving a motor vehicle or operating machinery (**Nightshift Sinus Clear & Cool only**)

## 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

### **MUCINEX SINUS-MAX SEVERE CONGESTION & PAIN CLEAR & COOL**

- 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

### **MUCINEX NIGHTSHIFT SINUS CLEAR & COOL**

- do not take more than directed (see Overdose warning)
- do not take more than 4 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

# MUCINEX-SINUS MAX SEVERE CONGESTION AND PAIN CLEAR AND COOL AND MUCINEX NIGHTSHIFT SINUS CLEAR AND COOL

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, triprolidine hydrochloride kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-116
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-116-66	1 in 1 CARTON	01/01/2019	01/29/2024
1		1 in 1 KIT		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	180 mL
Part 2	1 BOTTLE	180 mL

### Part 1 of 2

## MAXIMUM STRENGTH MUCINEX SINUS-MAX SEVERE CONGESTION AND PAIN CLEAR AND COOL

acetaminophen, guaifenesin, and phenylephrine hydrochloride solution

### Product Information

<b>Item Code (Source)</b>	NDC:63824-267
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

**D&C YELLOW NO. 10** (UNII: 35SW5USQ3G)

**EDETATE DISODIUM** (UNII: 7FLD91C86K)

**GLYCERIN** (UNII: PDC6A3C0OX)

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-267-66	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 final	part341	01/01/2019	

## Part 2 of 2

### MUCINEX NIGHTSHIFT SINUS CLEAR AND COOL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution

### Product Information

<b>Item Code (Source)</b>	NDC:63824-270
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL
<b>TRIPROLIDINE HYDROCHLORIDE</b> (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL



## Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-270-66	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 final	part341	01/01/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2019	01/29/2024

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