MAXIMUM STRENGTH MUCINEX SINUS-MAX SEVERE CONGESTION AND PAIN AND MUCINEX NIGHTSHIFT SINUS- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and 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.

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

Drug Facts

Active ingredients (in each 20 mL) Mucinex Sinus-Max Severe Congestion & Pain	***Purposes***
Acetaminophen 650mg	**Pain reliever**
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

Active ingredients (in each 20 mL) Mucinex Nightshift Sinus	***Purposes***
Acetaminophen 650mg	**Pain reliever/fever reducer**
Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant
Triprolidine HCl 2.5 mg	Antihistamine

Uses

Mucinex Sinus-Max Severe Congestion & Pain

- 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

- 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 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

- high blood pressure
- thyroid disease
- diabetes
- glaucoma **(Nightshift Sinus only)**
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis **(Nightshift Sinus 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 only)**

When using this product
- **do not use more than directed**
- excitability may occur, especially in children **(Nightshift Sinus only)**
- marked drowsiness may occur **(Nightshift Sinus only)**
- alcohol, sedatives, and tranquilizers may increase drowsiness **(Nightshift Sinus only)**
- avoid alcoholic drinks **(Nightshift Sinus only)**
- use caution when driving a motor vehicle or operating machinery **(Nightshift Sinus 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
- **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

- **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

Other information

- each 20 mL contains: **sodium 12 mg (Sinus-Max Severe Congestion & Pain only)** and **sodium 16 mg (Nightshift Sinus only)**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients (Mucinex Sinus-Max Severe Congestion & Pain)

anhydrous citric acid, edetate disodium, FD&C blue no.1, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate [1], xanthan gum

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1 may contain this ingredient

Inactive ingredients (Mucinex Nightshift Sinus)

ammonium glycyrrhizate, anhydrous citric acid, ascorbic acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, triacetin, triethyl citrate, water, xanthan gum

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 - Kit Carton

DAY & NIGHT
SINUS CONGESTION & PAIN RELIEF

MAXIMUM STRENGTH*

NDC 63824-115-66

Mucinex®
SINUS-MAX®

SEVERE CONGESTION
& PAIN

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

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

FOR
AGES 12+

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

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

FOR
AGES 12+

TWO – 6 FL OZ (180 mL) bottles
TOTAL – 12 FL OZ (360 mL)

No coating

Dist. by: RB Health (US), Parsippany, NJ 07054-0224 Tamper evident: Do not use if neckband on bottle cap is broken or missing.

Drug Facts (continued)

Active ingredients (in each 20 mL) Purposes
Mucinex Nightshift Sinus

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)

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nightshift Sinus only)

When using this product
- do not use more than directed
- excitability may occur, especially in children (Nightshift Sinus only)
- marked drowsiness may occur (Nightshift Sinus only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Nightshift Sinus only)
- avoid alcoholic drinks (Nightshift Sinus only)
- use caution when driving a motor vehicle or operating machinery (Nightshift Sinus 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
- 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
- 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

Other information
- each 20 mL contains: sodium 12 mg (Sinus-Max Severe Congestion & Pain only) and sodium 16 mg (Nightshift Sinus only)
- store at 20-25°C (68-77°F)
- do not refrigerate

Drug Facts

Active ingredients (in each 20 mL) Purposes
Mucinex Sinus-Max
Severe Congestion & Pain

Acetaminophen 650 mg	Pain reliever
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

Drug Facts (continued)

Uses ***Mucinex Sinus-Max Severe Congestion & Pain***
- 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
- temporarily relieves these common cold and flu symptoms:
  - cough
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  - 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
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Sore throat warning (Nightshift Sinus 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
- high blood pressure
- thyroid disease
- diabetes
- glaucoma (Nightshift Sinus only)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (Nightshift Sinus only)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

MAXIMUM STRENGTH MUCINEX SINUS-MAX SEVERE CONGESTION AND PAIN AND MUCINEX NIGHTSHIFT SINUS

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-115

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63824-115-66	1 in 1 CARTON	05/30/2022	

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

acetaminophen, guaifenesin, and phenylephrine hydrochloride solution

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

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

PHENYLEPHRINE HYDROCHLORIDE (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)	
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			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63824-266-66	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	05/30/2022	

Part 2 of 2

MUCINEX NIGHTSHIFT SINUS

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

Product Information

Item Code (Source)	NDC:63824-269
Route of Administration	ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-269-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	05/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/30/2022	

Labeler - RB Health (US) LLC (081049410)

Revised: 6/2023

RB Health (US) LLC