

**MUCINEX SINUS-MAX DAY PRESSURE, PAIN AND COUGH AND MUCINEX NIGHTSHIFT NIGHT SINUS MAXIMUM STRENGTH- 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.

Mucinex® Sinus-Max® Day Pressure, Pain & Cough and Mucinex Nightshift Night Sinus

Maximum Strength

Drug Facts

<i>Active ingredients (in each caplet) Mucinex Sinus-Max Day Pressure, Pain & Cough</i>	<i>Purposes</i>
Acetaminophen 325 mg	Pain reliever
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

<i>Active ingredients (in each caplet) Mucinex Nightshift Night Sinus</i>	<i>Purposes</i>
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

Mucinex Sinus-Max Day Pressure, Pain & Cough

- 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

Mucinex Nightshift Night Sinus

- temporarily relieves these common cold and flu symptoms:
 - cough
 - nasal congestion
 - minor aches and pains
 - sore throat
 - headache
 - sneezing
 - sinus congestion and pressure
 - runny nose
 - 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 (Nightshift Night 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
- diabetes
- high blood pressure
- thyroid disease
- glaucoma (***Nightshift Night Sinus only***)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (***Nightshift Night 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 Night Sinus only***)

When using this product

- **do not use more than directed**
- excitability may occur, especially in children (***Nightshift Night Sinus only***)
- marked drowsiness may occur (***Nightshift Night Sinus only***)
- alcohol, sedatives, and tranquilizers may increase drowsiness (***Nightshift Night Sinus only***)
- avoid alcoholic drinks (***Nightshift Night Sinus only***)
- use caution when driving a motor vehicle or operating machinery (***Nightshift Night 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 Day Pressure, Pain & Cough

- **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

Mucinex Nightshift Night Sinus

- **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

Mucinex Sinus-Max Day Pressure, Pain & Cough

croscarmellose sodium, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide

Inactive ingredients

Mucinex Nightshift Night Sinus

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 - Kit Carton

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

NDC 72854-243-20

MAXIMUM STRENGTH

Mucinex®

SINUS-MAX®

NIGHTSHIFT

DAY

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

ACTUAL SIZE

FOR AGES 12+

12 CAPLETS

NIGHT

SINUS

Acetaminophen – Pain Reliever/

Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Phenylephrine HCl – Nasal Decongestant

Tripolidine HCl – Antihistamine

NIGHTTIME

RELIEF FOR A BETTER

MORNING

✓COUGH ✓FEVER ✓SORE THROAT

✓RUNNY NOSE ✓SNEEZING

✓NASAL CONGESTION

ACTUAL SIZE

FOR AGES 12+

8 CAPLETS

FAST

RELEASE

TOTAL 20 CAPLETS

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

MAXIMUM STRENGTH

Mucinex
SINUS-MAX NIGHTSHIFT

DAY
PRESSURE, PAIN & COUGH

NIGHT
SINUS

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

NDC 72854-243-20

MAXIMUM STRENGTH

Mucinex
SINUS-MAX NIGHTSHIFT

DAY
PRESSURE, PAIN & COUGH

NIGHT
SINUS

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



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

ACTUAL SIZE FOR AGES 12+



FAST RELEASE



ACTUAL SIZE FOR AGES 12+

12 CAPLETS

TOTAL 20 CAPLETS

8 CAPLETS

MAXIMUM STRENGTH

Mucinex
SINUS-MAX NIGHTSHIFT

DAY
PRESSURE, PAIN & COUGH

Maximum Strength per 4-hour dose
Keep carton for full information.

NIGHT
SINUS

Do not take the Mucinex Sinus-Max Day Pressure, Pain & Cough and Mucinex Nightshift Night Sinus caplets at the same time. Always wait at least 4 hours before taking another dose of Mucinex caplets.
TAKE ONLY AS DIRECTED.

PARENTS:
Learn about your medicine online
www.StopTheMedicineAbuse.org

Questions?
1-866-MUCINEX (1-866-682-4639)
You may also report side effects to this phone number.

rb
HEALTH • HYGIENE • HOME
www.mucinex.com
Patents: www.rb.com/patents

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
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3176362 012721



LOT:
EXP.:
MADE IN:
3176362



Drug Facts

Active ingredients (in each caplet)

Purposes

Mucinex Sinus-Max Day Pressure, Pain & Cough

Acetaminophen 325 mg	Pain reliever
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3176362

Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant

Active ingredients (in each caplet)

Purposes

Mucinex Nightshift Night Sinus

Acetaminophen 325 mg.....	Pain reliever/fever reducer
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- headache
- cough

Mucinex Nightshift Night Sinus

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 - cough
 - sore throat
 - sinus congestion and pressure
 - itching of the nose or throat
 - itchy, watery eyes due to hay fever
 - temporarily reduces fever
 - controls cough to help you get to sleep
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- sneezing
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010521 PEEL CORNER TO HEAD COMPLETE DRUG FACTS AND INFORMATION

Reseal Area

Drug Facts (continued)

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.

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- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (*Nightshift Night Sinus only*)
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- cough that occurs with too much phlegm (mucus)
- heart disease
- diabetes
- thyroid disease

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- use caution when driving a motor vehicle or operating machinery (*Nightshift Night 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

Hinge

Hinge

Drug Facts (continued)

- 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.

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Mucinex Nightshift Night Sinus

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Other information ■ store at 20-25°C (68-77°F)

Inactive ingredients

Mucinex Sinus-Max Day Pressure, Pain & Cough

croscarmellose sodium, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide

Inactive ingredients

Mucinex Nightshift Night Sinus

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.

MUCINEX SINUS-MAX DAY PRESSURE, PAIN AND COUGH AND MUCINEX NIGHTSHIFT NIGHT SINUS MAXIMUM STRENGTH

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-243
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:72854-243-10	1 in 1 CARTON	07/01/2021	
1		1 in 1 KIT		
2	NDC:72854-243-20	2 in 1 CARTON	07/01/2021	
2		1 in 1 KIT		
3	NDC:72854-243-40	4 in 1 CARTON	07/01/2021	
3		1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	6
Part 2	1 BLISTER PACK	4

Part 1 of 2

MAXIMUM STRENGTH MUCINEX SINUS-MAX PRESSURE, PAIN AND COUGH

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

Product Information

Item Code (Source)	NDC:63824-242
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	VV;MSC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 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	

Part 2 of 2

MUCINEX NIGHTSHIFT SINUS MAXIMUM STRENGTH

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

Product Information

Item Code (Source)	NDC:72854-240
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPROVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
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;LOGOcrescentmoonplus
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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	

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)