MUCINEX SINUS-MAX DAY NIGHT- acetaminophen, diphenhydramine hydrochloride, guaifenesin, phenylephrine 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 Night
Maximum Strength

Drug Facts

Active ingredients (in each caplet) ***Mucinex SINUS-MAX DAY***	***Purposes***
Acetaminophen 325 mg	**Pain reliever**
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each caplet) ***Mucinex SINUS-MAX NIGHT***	***Purposes***
Acetaminophen 325 mg	**Pain reliever**
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

Mucinex SINUS-MAX DAY

- 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 SINUS-MAX NIGHT

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
  - runny nose
  - sneezing

    - cough
- temporarily promotes nasal and/or sinus drainage

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.
- with any other product containing diphenhydramine, even one used on the skin ***(NIGHT only)***
- 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
- glaucoma ***(NIGHT only)***
- a breathing problem such as emphysema or chronic bronchitis ***(NIGHT 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 ***(NIGHT only)***

When using this product

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

- **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 (Mucinex SINUS-MAX DAY only)

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 SINUS-MAX NIGHT only)

croscarmellose sodium, crospovidone, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, ferric oxide yellow, methacrylic acid – ethyl acrylate copolymer (1:1) type A, mica, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone,

sodium bicarbonate, 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

MAXIMUM STRENGTH

NDC 63824-204-20

FOR AGES 12+

Mucinex®
SINUS-MAX®

Actual Size

DAY

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

- Relieves Sinus Pressure, Headache & Congestion
- Thins & Loosens Mucus

12
CAPLETS

Actual Size

NIGHT

Acetaminophen - Pain Reliever
Diphenhydramine HCl - Antihistamine/Cough Suppressant
Phenylephrine HCl - Nasal Decongestant

- Relieves Nasal Congestion, Sinus Pressure & Pain
- Relieves Runny Nose, Sneezing & Cough

8
CAPLETS

TOTAL
20 CAPLETS

MAXIMUM STRENGTH

Mucinex SINUS-MAX DAY NIGHT

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.

LOT:
EXP.:
MADE IN:
3165983

MAXIMUM STRENGTH

FOR AGES 12+

NDC 63824-204-20

Mucinex® SINUS-MAX®

Actual Size

DAY

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

✓ Relieves Sinus Pressure, Headache & Congestion
✓ Thins & Loosens Mucus

12 CAPLETS

TOTAL 20 CAPLETS

NIGHT

Actual Size

Acetaminophen – Pain Reliever
Diphenhydramine HCl – Antihistamine/Cough Suppressant
Phenylephrine HCl – Nasal Decongestant

✓ Relieves Nasal Congestion, Sinus Pressure & Pain
✓ Relieves Runny Nose, Sneezing & Cough

8 CAPLETS

HEALTH • HYGIENE • HOME

Do not take the Mucinex SINUS-MAX DAY and NIGHT caplets at the same time. Always wait at least 4 hours before taking another dose of Mucinex caplets. Do not take more than a total of 12 caplets in any 24-hour period.

Take only as directed. www.mucinex.com 100720 3165983

Patents: www.rb.com/patents Dist by: RB Health (US), Parsippany, NJ 07054-0224 ©2020 RB Health

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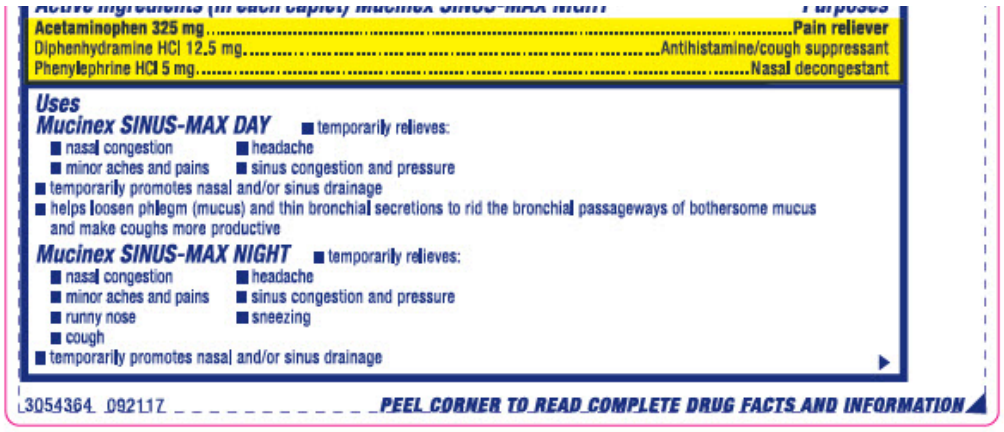
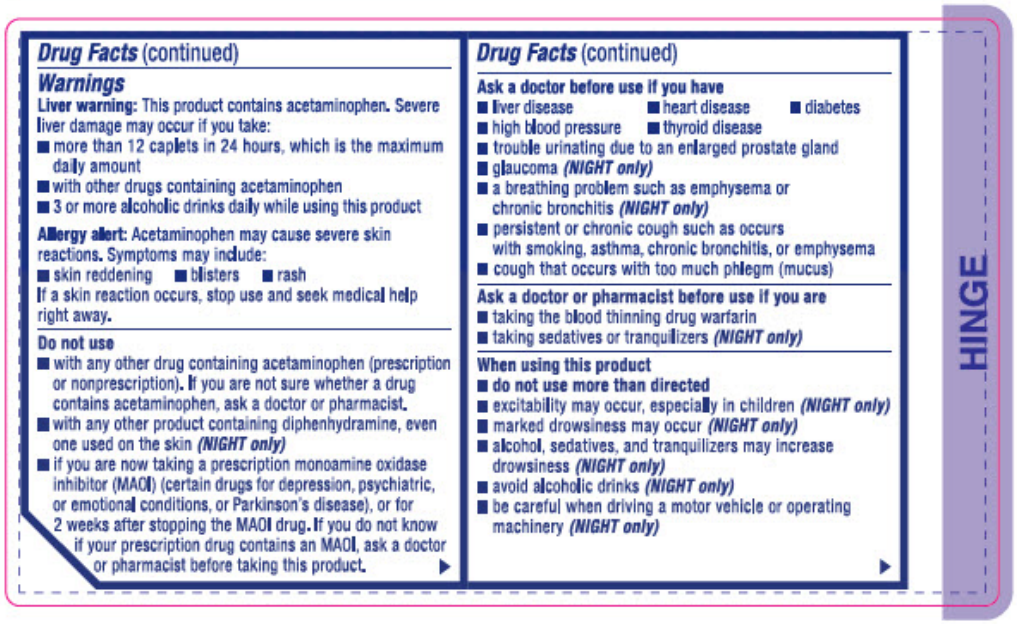
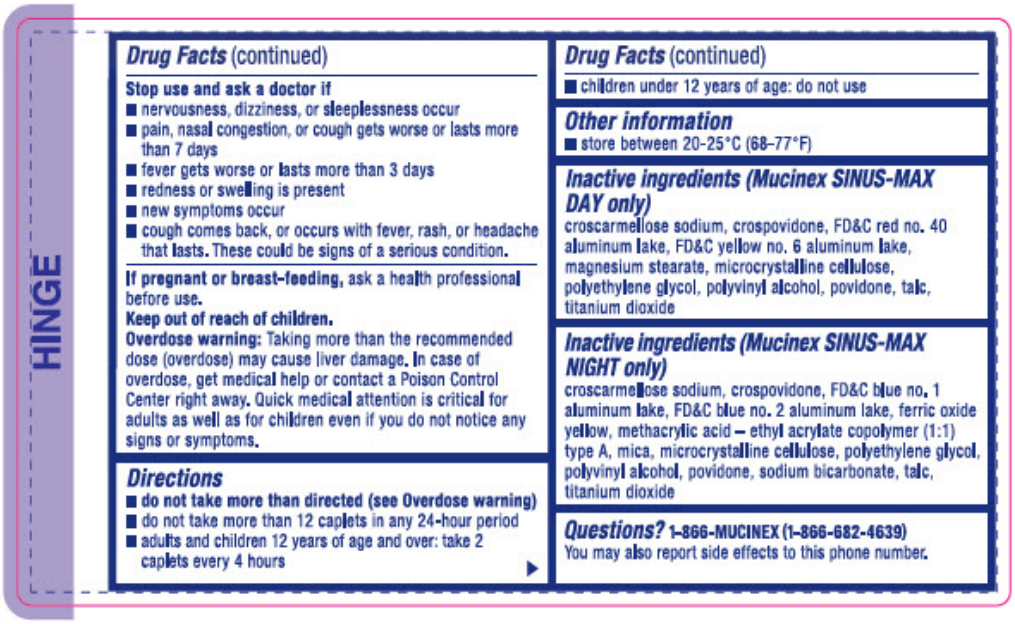
Drug Facts

Active ingredients (in each caplet) Mucinex SINUS-MAX DAY	Purposes
Acetaminophen 325 mg	Pain reliever
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each caplet) Mucinex SINUS-MAX NIGHT Purposes







MUCINEX SINUS-MAX DAY NIGHT

acetaminophen, diphenhydramine hydrochloride, guaifenesin, phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-204

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-204-20	1 in 1 CARTON	08/25/2015	09/28/2024
2	NDC:63824-204-40	4 in 1 CARTON	06/01/2020	06/19/2025
2		1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	12
Part 2	2 BLISTER PACK	8

Part 1 of 2

MUCINEX SINUS-MAX DAY

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet, coated

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	VVV;CS
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	08/25/2015	

Part 2 of 2

MUCINEX SINUS-MAX NIGHT

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride tablet, coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	VVV;CF
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	08/25/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/25/2015	06/19/2025

Labeler - RB Health (US) LLC (081049410)

Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	manufacture(63824-204)