MUCINEX SINUS-MAX DAY AND NIGHT MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, and 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 and Night
Maximum Strength

Drug Facts

Active ingredients (in each liquid gel) ***Mucinex SINUS-MAX DAY***	***Purposes***
Acetaminophen 325 mg	**Pain reliever**
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each liquid gel) ***Mucinex SINUS-MAX NIGHT***	***Purposes***
Acetaminophen 325 mg	**Pain reliever**
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - cough
  - minor aches and pains
  - sinus congestion and pressure
  - runny nose and sneezing ***(NIGHT only)***
- 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 ***(DAY only)***

Warnings

Liver warning

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

- more than 12 liquid gels 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.
- 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 liquid gels in any 24-hour period
- adults and children 12 years of age and over: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat

Inactive ingredients (DAY only)

FD&C yellow no. 6, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

Inactive ingredients (NIGHT only)

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

Questions?

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

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

PRINCIPAL DISPLAY PANEL - Kit Carton

Fast Dissolving Liquid Gels!

NDC 72854-204-24

MAXIMUM STRENGTH

Mucinex®
SINUS-MAX®

DAY

Acetaminophen – Pain Reliever
Dextromethorphan HBr - Cough Suppressant
Guaifenesin – Expectorant
Phenylephrine HCl – Nasal Decongestant

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

Actual Size

16
LIQUID GELS
(Liquid Filled
Capsules)

NIGHT

Acetaminophen – Pain Reliever
Dextromethorphan HBr - Cough Suppressant
Doxylamine Succinate - Antihistamine
Phenylephrine HCl - Nasal Decongestant

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

Actual Size

8
LIQUID GELS
(Liquid Filled
Capsules)

FOR AGES 12+

TOTAL 24
LIQUID GELS

MAXIMUM STRENGTH

Mucinex SINUS-MAX

DAY NIGHT

VALUE PACK

24 LIQUID GELS

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

Fast Dissolving Liquid Gels!

MAXIMUM STRENGTH

NDC 72854-204-24

Mucinex®

SINUS-MAX®

DAY

NIGHT

Acetaminophen – Pain Reliever
Dextromethorphan HBr - Cough Suppressant
Guaifenesin – Expectorant
Phenylephrine HCl – Nasal Decongestant

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

Actual Size

FOR AGES 12+

Acetaminophen – Pain Reliever
Dextromethorphan HBr - Cough Suppressant
Doxylamine Succinate - Antihistamine
Phenylephrine HCl - Nasal Decongestant

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

Actual Size

16 LIQUID GELS (Liquid Filled Capsules)

TOTAL 24 LIQUID GELS

8 LIQUID GELS (Liquid Filled Capsules)

Questions?
1-888-MUCINEX (1-888-682-4639)
You may also report side effects to this phone number.

HEALTH • HYGIENE • HOME

www.mucinex.com
Patients: www.rb.com/patients

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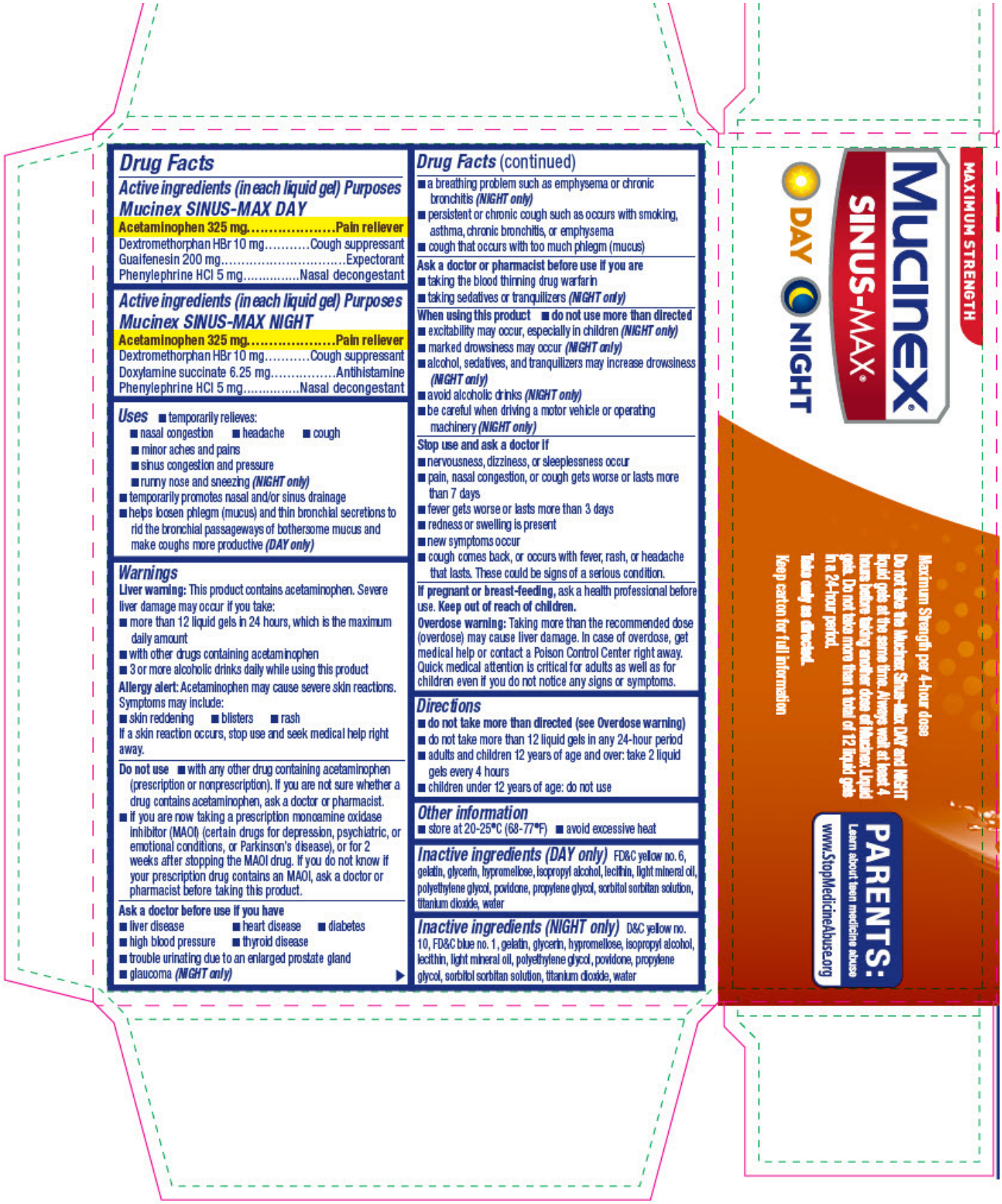

MUCINEX SINUS-MAX DAY AND NIGHT MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, and phenylephrine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72854-204

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72854-204-24	1 in 1 CARTON	07/26/2021	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2

MUCINEX SINUS-MAX DAY MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled

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
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**
FD&C yellow no. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	OVAL	**Size**	26mm
Flavor		**Imprint Code**	AR01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	07/26/2021	

Part 2 of 2

MUCINEX SINUS-MAX NIGHT MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride capsule, liquid filled

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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength

D&C yellow no. 10 (UNII: 35SW5USQ3G)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	21mm
Flavor		**Imprint Code**	AR03
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	07/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/26/2021	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2021 RB Health (US) LLC