SINUS MAX RELIEF DAY AND NIGHT- acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, and phenylephrine hydrochloride
TOPCO ASSOCIATES 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.

Sinus Max Relief Day and Night

Drug Facts

Active ingredients (in each softgel) DAY	***Purposes***
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each softgel) NIGHT	***Purposes***
Acetaminophen 325 mg	Pain reliever/fever reducer
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 & pains
  - sinus congestion & 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 softgels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

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 these products
- **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 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

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients (DAY only)

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Inactive ingredients (NIGHT only)

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

1-888-423-0139

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 36800-812-24

*Compare to the active ingredients in
Mucinex® Sinus Max® Day

MAXIMUM STRENGTH**

Sinus Relief
Day

PAIN RELIEVER - ACETAMINOPHEN
COUGH SUPPRESSANT-
DEXTROMETHORPHAN HBR
EXPECTORANT - GUAIFENESIN
NASAL DECONGESTANT -
PHENYLEPHRINE HCL

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

DAY TIME
FOR AGES 12+

FAST
DISSOLVING
SOFTGELS!

actual size

16 SOFTGELS
(Liquid Filled Capsules)

*Compare to the active ingredients in Mucinex® Sinus Max® Night

MAXIMUM STRENGTH**

Sinus Relief
Night

PAIN RELIEVER - ACETAMINOPHEN
COUGH SUPPRESSANT-
DEXTROMETHORPHAN HBR
ANTIHISTAMINE -
DOXYLAMINE SUCCINATE
NASAL DECONGESTANT -
PHENYLEPHRINE HCL

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

NIGHT TIME

FOR AGES 12+

FAST
DISSOLVING
SOFTGELS!

actual size

8 SOFTGELS
(Liquid Filled Capsules)

NDC 36800-812-24

*Compare to the active ingredients in Mucinex® Sinus Max® Day

MAXIMUM STRENGTH*

Sinus Relief Day

PAIN RELIEVER - **ACETAMINOPHEN**

COUGH SUPPRESSANT- **DEXTROMETHORPHAN HBR**

EXPECTORANT - **GUAIFENESIN**

NASAL DECONGESTANT - **PHENYLEPHRINE HCL**

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

DAY TIME
FOR AGES 12+

FAST DISSOLVING SOFTGELS!

actual size

16 SOFTGELS
(Liquid Filled Capsules)

*Compare to the active ingredients in Mucinex® Sinus Max® Night

MAXIMUM STRENGTH*

Sinus Relief Night

PAIN RELIEVER - **ACETAMINOPHEN**

COUGH SUPPRESSANT- **DEXTROMETHORPHAN HBR**

ANTIHISTAMINE - **DOXYLAMINE SUCCINATE**

NASAL DECONGESTANT - **PHENYLEPHRINE HCL**

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

NIGHT TIME
FOR AGES 12+

FAST DISSOLVING SOFTGELS!

actual size

8 SOFTGELS
(Liquid Filled Capsules)

*These products are not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Sinus-Max® Day & Night Softgel

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT

Drug Facts

Active ingredients (in each softgel) DAY	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

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  - sinus congestion & pressure
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- 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)***

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- 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)***

Drug Facts (continued)

- 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 these products

- **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 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: In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients (DAY only)

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Inactive ingredients (NIGHT only)

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

Drug Facts (continued)

Questions or comments?

1-888-423-0139

**Per 4-hour dose

Do not take DAY & NIGHT softgels at the same time. Do not take more than a total of 12 softgels in a 24-hour period. Do not take the first dose of the NIGHT softgels sooner than 4 hours after the last dose of the DAY softgels unless directed by a doctor.

Take only as directed

Keep outer carton for complete warnings and product information

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

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LOT:

EXP:

SINUS MAX RELIEF DAY AND NIGHT

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-765

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:36800-765-12	1 in 1 CARTON	05/01/2021	

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

Part 1 of 2

SINUS MAX RELIEF DAY

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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	782
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	05/01/2021	

Part 2 of 2

SINUS MAX RELIEF NIGHT

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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	789
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	05/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/01/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 3/2021 TOPCO ASSOCIATES LLC