DAYTIME NIGHTTIME SINUS RELIEF MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl,guaifenes in CVS Pharmacy

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.

Drug Facts

Active ingredients in Daytime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Active ingredients in Nighttime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCI 5 mg

Purpose for Daytime

Pain reliever

Cough suppressant

Expectorant

Nasal decongestant

Purpose for Nighttime

Pain reliever

Cough suppressant

Antihistamine

Nasal decongestant

Uses

DAYTIME

- temporarily relieves
 - nasal congestion
 - headache
 - cough due to inhaled irritants
 - sinus congestion and pressure
 - minor aches and pains

- 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

NIGHTTIME

- temporarily relieves
 - o nasal congestion
 - cough due to inhaled irritants
 - headache
 - sinus congestion and pressure
 - minor aches and pains
 - runny nose and sneezing
- promotes nasal and/or sinus drainage

Warnings

DAYTIME and NIGHTTIME

Liver warning: These products contain acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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

DAYTIME and NIGHTTIME

- 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

DAYTIME

- liver disease
- high blood pressure
- diabetes
- heart disease
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

NIGHTTIME

- liver disease
- high blood pressure
- diabetes
- heart disease
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or 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

DAYTIME

taking the blood thinning drug warfarin

NIGHTTIME

taking the blood thinning drug warfarin taking sedatives or tranquilizers

When using this product,

DAYTIME

do not use more than directed

NIGHTTIME

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

Stop use and ask a doctor if

DAYTIME and NIGHTTIME

- 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,

DAYTIME and NIGHTTIME

ask a health professional before use.

Keep out of reach of children.

DAYTIME and NIGHTTIME

Overdose warning: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

DAYTIME

- do not take more than directed (see Overdose warning)
- do not take more than 12 softgels (Daytime and NightTime) 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
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

NIGHTTIME

- do not take more than directed (see Overdose warning)
- do not take more than 12 softgels (Daytime and Nighttime) 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
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

Other information

DAYTIME and **NIGHTTIME**

- swallow whole; do not crush, chew, or dissolve
- store between 15-30°C (59-86F)
- avoid excessive heat

Inactive ingredients

DAYTIME

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

NIGHTTIME

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

Questions or comments?

DAYTIME and NIGHTTIME

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Maximum Strength Mucinex \$ SINUS-MAX \$ Day and Maximum Strength Mucinex \$ SINUS-MAX \$

Night**

DAYTIME

MAXIMUM STRENGTH

Daytime

Sinus Relief

ACETAMINOPHEN - 325 mg Pain reliever

DEXTROMETHORPHAN - 10 mg Cough Suppressant

GUAIFENESIN - 200 mg Expectorant

PHENYLEPHRINE HCI - 5 mg Nasal Decongestant

- Relieves sinus pressure, headache & congestion
- Controls cough
- thins & loosens mucus

LIQUID GELS

NIGHTTIME

MAXIMUM STRENGTH

Nighttime

Sinus Relief

ACETAMINOPHEN - 325 mg Pain reliever

DEXTROMETHORPHAN HBr - 10 mg Cough Suppressant

DOXYLAMINE SUCCINATE - 6.25 mg Antihistamine

PHENYLEPHRINE HCI - 5 mg Nasal Decongestant

- Relieves nasal congestion, sinus pressure & pain
- Controls cough
- Controls runny nose and sneezing

LIQUID GELS

(*Liqui-Filled Capsules)

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Sinus-Max® Day and Maximum Strength Mucinex® SINUS-MAX® Night.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CVS Pharmacy, Inc,

One CVS Drive, Woonsocket, RI 02896

CVS.com® 1800-SHOP CVS

Product Label



CVS Health DAY & NIGHT TWIN PACK Maximum Strength DayTime NightTime Sinus Relief

DAYTIME NIGHTTIME SINUS RELIEF MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl, guaifenesin kit

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-554

]	Packaging						
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:59779-554-24	1 in 1 CARTON; Type 0: Not a Combination Product	05/31/2016	02/01/2022			

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

Part 1 of 2

NIGHTTIME SINUS RELIEF MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci capsule

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg		
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		
PHENYLEPHRINE HYDRO CHLO RIDE (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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE (UNII: FZ989 GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
SHELLAC (UNII: 46N107B71O)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	GREEN	Score	no score	
Shape	CAPSULE	Size	20 mm	
Flavor		Imprint Code	116	
Contains				

Packaging	Packaging				
# Item Code Package Description Marketing Start Date Marketing End I					
1	8 in 1 CARTON				
1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Inform	nation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/31/2016	

Part 2 of 2

DAYTIME SINUS RELIEF MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci capsule

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9 127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6O92ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color ORANGE Score no score				
Shape	CAPSULE	Size	20 mm	
Flavor		Imprint Code	341	
Contains				

I	ackaging			
# Item Code Package Description		Package Description	Marketing Start Date	Marketing End Date
	L	16 in 1 CARTON		
	L	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information						
Marketing Category	Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Dat					
OTC MONOGRAPH FINAL	part341	05/31/2016	02/01/2022			
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC MONOGRAPH FINAL	part341	05/31/2016	02/01/2022			

Labeler - CVS Pharmacy (062312574)

Revised: 10/2019 CVS Pharmacy