# SINUS RELIEF DAYTIME NIGHTTIME- acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl Kroger Company

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Kroger 44-615694

### Active ingredients (in each caplet) (Sinus Day)

Acetaminophen 325 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

### **Purpose**

Pain reliever Expectorant Nasal decongestant

### Active ingredients (in each caplet) (Sinus Night)

Acetaminophen 325 mg Diphenhydramine HCl 12.5 mg Phenylephrine HCl 5 mg

### **Purpose**

Pain reliever Antihistamine/cough suppressant Nasal decongestant

#### Uses

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

## Warnings

**Liver warning**: This product contains 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

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- with any other product containing diphenhydramine, even one used on skin (Nighttime only)

## Ask a doctor before use if you have

- heart disease
- high blood pressure
- liver disease
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis (Nighttime only)
- glaucoma (Nighttime only)

## Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nighttime only)

## When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children (Nighttime only)
- marked drowsiness may occur (Nighttime only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)
- be careful when driving a motor vehicle or operating machinery (Nighttime only)

avoid alcoholic beverages (Nighttime 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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing. Do not take DAY & NIGHT at the same time.

#### **Directions**

- do not use more than directed
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

#### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

## Inactive ingredients (Daytime only)

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

## Inactive ingredients (Nighttime only)

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and

ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

#### Questions or comments?

1-800-426-9391

### Principal display panel

COMPARE TO the active ingredients of MAXIMUM STRENGTH MUCINEX® SINUSMAX® DAY & NIGHT

\*See bottom panel

NDC 30142-616-09

**OUR PHARMACIST RECCOMMENDED** 

Maximum Strength

FOR AGES 12+

Kroger®

Sinus Relief

NIGHTTIME

DAYTIME **Acetaminophen**/Pain Reliever

Acetaminophen/ Pain Reliever Diphenhydramine HCl/

**Guafenesin** / Expectorant Antihistamine/Cough Suppressant

Phenylephrine HCI/ Nasal Decongestant Phenylephrine HCI/ Nasal Decongestant

**RELIEVES:** 

Sinus Pressure RELIEVES:

Headache Nasal Congestion
& Congestion Sinus Pressure & Pain
Thins & Loosens Mucus Runny Nose

actual size Sneezing & Cough

12 CAPLETS actual size 8 CAPLETS

\*Maximum Strength Mucinex® SINUS-MAX® Day & Night is a registered trademark of Reckitt Benckiser LLC, Slough, United Kingdom. Reckitt Benckiser is not aliated with The Kroger Co. or these products.

50844 ORG051761569409

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

For More Product Information, Scan UPC Using Your KrogerApp or Call 800-632-6900

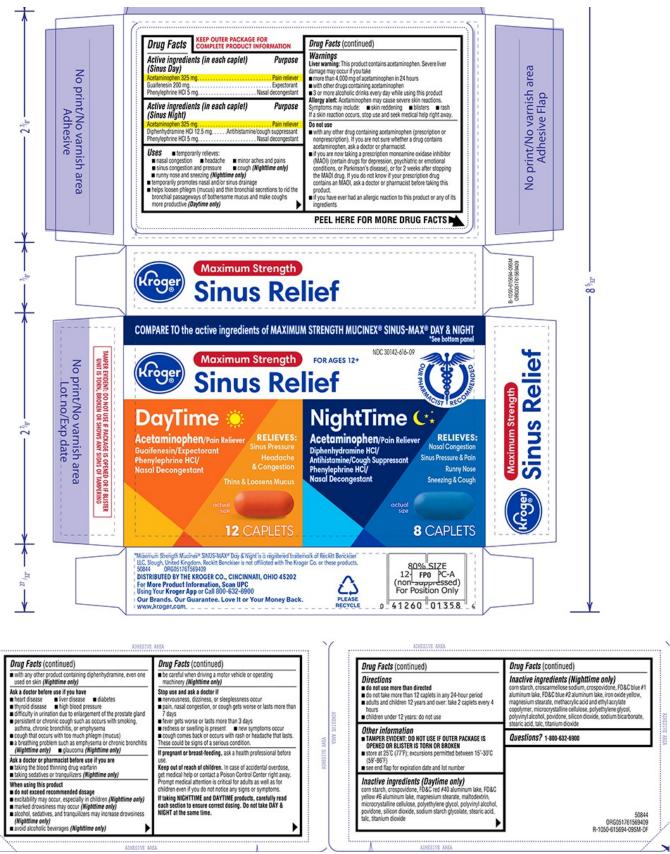
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www.kroger.com

#### PLEASE RECYCLE

#### TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER

UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



## SINUS RELIEF DAYTIME NIGHTTIME

acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-616

ı	P	ackaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:30142-616- 09	1 in 1 CARTON; Type 0: Not a Combination Product	06/01/2021		

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

## Part 1 of 2

## SINUS RELIEF DAYTIME

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

Product Information		
Item Code (Source)	NDC:30142-972	
Route of Administration	ORAL	

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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			
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPOVIDONE (UNII: 2S7830E561)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color orange Score no score			no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	44;615	
Contains				

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		12 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 Drug	M012	06/01/2021		

## Part 2 of 2

## **SINUS RELIEF NIGHTTIME**

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

<b>Product Information</b>	
Item Code (Source)	NDC:30142-986
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	

<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
,	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Ingredient Name  STARCH, CORN (UNII: O8232NY3SJ)  CROSCARMELLOSE SODIUM (UNII: M280L1HH48)  CROSPOVIDONE (UNII: 2S7830E561)  FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)  FD&C BLUE NO. 2ALUMINUM LAKE (UNII: 4AQJ3LG584)  FERRIC OXIDE YELLOW (UNII: EX43802MRT)  MAGNESIUM STEARATE (UNII: 70097M6I30)  METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)  MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)  CROSPOVIDONE (UNII: 2S7830E561)  FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)  FD&C BLUE NO. 2ALUMINUM LAKE (UNII: 4AQJ3LG584)  FERRIC OXIDE YELLOW (UNII: EX43802MRT)  MAGNESIUM STEARATE (UNII: 70097M6I30)  METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	ngth
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MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
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POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	44;694	
Contains				

l	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 Marketing I Date Date				
OTC Monograph Drug	M012	06/01/2021				

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	06/01/2021	

# Labeler - Kroger Company (006999528)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		038154464	pack(30142-616)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867837	manufacture(30142-616) , pack(30142-616)		

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(30142-616)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(30142-616)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		117025878	manufacture(30142-616)		

Revised: 7/2023 Kroger Company