# SINUS RELIEF DAYTIME, NIGHTTIME, MAXIMUM STRENGTH- acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl CVS PHARMACY

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CVS 44-615694-09

# 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 these common cold symptoms:
- 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)

- use caution 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 overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not take DAYTIME and NIGHTTIME products 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

- each caplet contains: sodium 3 mg (Daytime only)
- 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

**♥CVS**Health™

Daytime

MAXIMUM STRENGTH Sinus Relief

**ACETAMINOPHEN**- Pain reliever

GUAIFENESIN - Expectorant PHENYLEPHRINE HCl - Nasal

decongestant

Relieves:

Sinus pressure &

Congestion, Headache

Thins & loosens mucus

**Actual Size** 

**10** CAPLETS For Ages 12 +

Sinus Pain

NDC 69842-882-09

Nighttime

**MAXIMUM STRENGTH** 

**Sinus Relief** 

**ACETAMINOPHEN-** Pain reliever

**DIPHENHYDRAMINE HCI-**

Antihistamine/

Cough suppressant

PHENYLEPHRINE HCI - Nasal

decongestant

Relieves:

Nasal congestion, Sinus

pressure & Pain, Runny nose,

Sneezing & Cough

**Actual Size** 

**10** CAPLETS For Ages 12 +

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

50844 REV0723A61569409

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Money Back Guarantee

#### Drug Facts (continued)

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 philegm (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

- when using this product

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  excitability may occur, especially in ohlidren (Nighttime only)

  marked drowsiness may occur (Nighttime only)

  alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)

#### Drug Facts (continued)

 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+800-222-1922) 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

Maximum Strength Mucinex® SINUS-MAX® Day & Night. 50844 ORG051761569409

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark

#### Drug Facts (continued)

#### Directions

- do not take 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 numb

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, silcon disoide, sodium starch glycolate, stearic acid,
talc, titanium dioxide

#### Drug Facts (continued)

#### Inactive ingredients (Nighttime only)

corn starch, croscarmellose sodium, crospovidone, FD&C b #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide vellow, 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? 1.886.426.9391

ORG051761569409 R-0231-61569409SMHDF

V-19849

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# KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

Guaifenesin 200 mg Expectorant Phenylephrine HCl 5 mg Nasal decongestant

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

Diphenhydramine HCl 12.5 mg .......Antihistamine/cough suppressant Phenylephrine HCl 5 mg 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 philegm (mucus) and thin bronchial secretions to rid
  the bronchial passageways of bothersome mucus and make coughs
  more productive (Daytime only)

#### Drug Facts (continued)

Purpose

Purpose

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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
- with any other drug contaming 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 (MADI) (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
- if you have ever had an alleroic reaction to this product or any of its ingredients

PEEL HERE FOR MORE DRUG FACTS

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CVSHealth

**MAXIMUM STRENGTH** Sinus Relief

Sinus Pain

MAXIMUM STRENGTH Sinus Relief

CVSHealth.

Compare to the active ingredients in Maximum Strength Mucinex® SINUS-MAX® Day & Night\*

Sinus Pain NDC 69842-882-09

Daytime

# MAXIMUM STRENGTH Sinus Relief

ACETAMINOPHEN - Pain rei



MAXIMUM STRENGTH

# Sinus Relief

ACETAMINOPHEN - Pain reliever **DIPHENHYDRAMINE HCI - Antihistamine/** PHENYLEPHRINE HCI - Nasal decongestant

Nasal congestion, Sinus pressure & Pain, Runny nose Sneezing & Cough



10 CAPLETS For Ages 12+

CVS 615694

# SINUS RELIEF DAYTIME, NIGHTTIME, MAXIMUM STRENGTH

acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-882

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:69842-882- 09	1 in 1 CARTON; Type 0: Not a Combination Product	07/01/2017		

Quant	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BLISTER PACK	10		
Part 2	1 BLISTER PACK	10		

# Part 1 of 2

# SINUS RELIEF DAYTIME, MAXIMUM STRENGTH

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

# **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	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: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: 08232NY3SJ)				
CROSPOVIDONE, UNSPECIFIED (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: 3WJQ0SDW1A)	
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
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;615
Contains			

Packaging					
# Item Package Description		Marketing Start Date	Marketing End Date		
	1		10 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	06/30/2013			

# Part 2 of 2

# SINUS RELIEF NIGHTTIME, MAXIMUM STRENGTH

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information		
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 (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	Ema	

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
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				

P	Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1		10 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	07/01/2017				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M012	07/01/2017				

# Labeler - CVS PHARMACY (062312574)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		038154464	pack(69842-882)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867837	manufacture(69842-882) , pack(69842-882)		

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		832867894	manufacture(69842-882)		

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		967626305	pack(69842-882)		

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
LNK International, Inc.		117025878	manufacture(69842-882)		

Revised: 2/2024 CVS PHARMACY