## SINUS PRESSURE AND PAIN DAYTIME NIGHTTIME MAXIMUM STRENGTHacetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl Walgreen Company

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Walgreens 44-615694-10-SMH

## 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 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

- 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

**DAY & NIGHT PACK NDC 0363-6156-10** 

WALGREENS •
 PHARMACIST RECOMMENDED<sup>†</sup>
 Walgreens

DAYTIME
Sinus
Pressure
& Pain
ACETAMINOPHEN
PAIN RELIEVER
GUAIFENESIN
EXPECTORANT
PHENYLEPHRINE HCI
NASAL DECONGESTANT
Maximum Strength
24 CAPLETS
ACTUAL SIZE

NIGHTTIME
Sinus
Pressure
& Pain
ACETAMINOPHEN
PAIN RELIEVER
DIPHENHYDRAMINE HCI
ANTIHISTAMINE
COUGH SUPPRESSANT
PHENYLEPHRINE HCI
NASAL DECONGESTANT
Maximum Strength
16 CAPLETS
ACTUAL SIZE

#### TOTAL 40 CAPLETS

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN,

**BROKEN OR SHOWS ANY SIGNS OF TAMPERING** 

Do Not Take Daytime and Nighttime Products at the Same Time.

<sup>†</sup>Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

50844 REV0723A61569410

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DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
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**Walgreens 44-615694** 

## SINUS PRESSURE AND PAIN DAYTIME NIGHTTIME MAXIMUM **STRENGTH**

acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

#### **Product Information**

l	Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:0363-6156- 10	1 in 1 CARTON; Type 0: Not a Combination Product	06/02/2018			

Quant	Quantity of Parts					
Part #	Package Quantity	Total Product Quantity				
Part 1	2 BLISTER PACK	24				
Part 2 2 BLISTER PACK		16				

## Part 1 of 2

# SINUS PRESSURE AND PAIN DAYTIME MAXIMUM STRENGTH

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

## **Product Information**

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: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg			

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
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: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

<b>Product Charac</b>	Product Characteristics			
Color	orange	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	44;615	
Contains				

Pac	Packaging						
# Item Package Description		Marketing Start Date	Marketing End Date				
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product					

Marketing Information						
Marketing Category	Marketing End Date					
OTC Monograph Drug	M012	06/02/2018				

## Part 2 of 2

# SINUS PRESSURE AND PAIN 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					
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 - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg			

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			

CROSPOVIDONE, UNSPECIFIED (UNII: 257830E561)

FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)

FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)

FERRIC OXIDE YELLOW (UNII: EX43802MRT)

MAGNESIUM STEARATE (UNII: 70097M6I30)

METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)

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				

	Packaging					
# Item Package Desc			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 Drug	M012	06/02/2018				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	06/02/2018			

## Labeler - Walgreen Company (008965063)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		038154464	pack(0363-6156)	

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867837	manufacture(0363-6156), pack(0363-6156)		

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	manufacture(0363-6156)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		967626305	pack(0363-6156)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		117025878	manufacture(0363-6156)	

Revised: 3/2024 Walgreen Company