SINUS PE CONGESTION DAYTIME NIGHTTIME- diphenhydramine hcl, phenylephrine hcl Meijer Distribution, Inc.

Meijer 44-453485

Active ingredient (in each tablet) (Sinus Day)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Active ingredients (in each tablet) (Sinus Night)

Diphenhydramine HCl 25 mg Phenylephrine HCl 10 mg

Purpose

Antihistamine Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - nasal congestion
 - sneezing (Nighttime only)
 - runny nose (Nighttime only)
 - itchy, watery eyes (Nighttime only)
 - itching of the nose or throat (Nighttime only)
- temporarily relieves these symptoms due to the common cold:
 - nasal congestion
 - sneezing (Nighttime only)
 - runny nose (Nighttime only)
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

- 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.
- with any other product containing diphenhydramine, even one used on skin (Nighttime only)

Ask a doctor before use if you have

- heart disease
- diabetes

- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- 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 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)
- avoid alcoholic beverages (Nighttime only)
- use caution when driving a motor vehicle or operating machinery (Nighttime only)

Stop use and ask a doctor if

- symptoms do not improve within 7 days or occur with fever
- nervousness, dizziness, or sleeplessness occur

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.

Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

- adults and children 12 years and over
 - take 1 tablet every 4 hours
 - do not take more than 6 tablets in 24 hours
- children under 12 years: do not use

Other information

- each tablet contains: calcium 25 mg (Nighttime 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)

croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

Inactive ingredients (Nighttime only)

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum

lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Principal display panel

meijer®

COMBO PACK

20 TABLETS TOTAL

NDC 79481-4534-1

COMPARE TO
DAYTIME SUDAFED PE®
SINUS CONGESTION ACTIVE INGREDIENT*
COMPARE TO
NIGHTTIME SUDAFED PE®
SINUS CONGESTION
ACTIVE INGREDIENTS*

NON-DROWSY
Daytime
Sinus PE Congestion
PHENYLEPHRINE HCI 10 mg

NASAL DECONGESTANT Pseudoephedrine Free

Relieves

Nasal Congestion

12 Tablets actual size Nighttime

Sinus PE Congestion DIPHENHYDRAMINE HCI 25 mg PHENYLEPHRINE HCI 10 mg

Antihistamine Nasal Decongestant

Pseudoephedrine Free

Relieves

Nasal Congestion,

Runny Nose

8

Tablets actual size

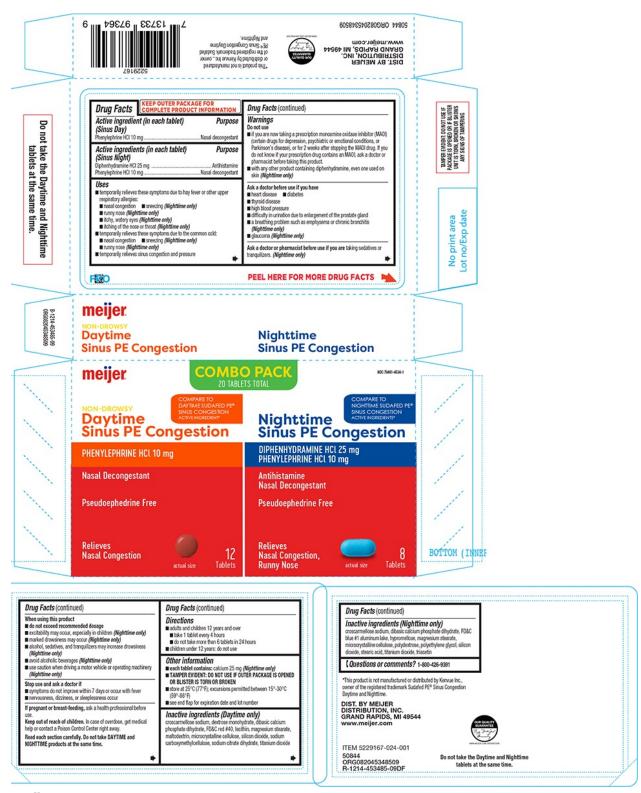
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Sudafed PE® Sinus Congestion Daytime and Nighttime.

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DIST. BY MEIJER DISTRUBUTION, INC. GRAND RAPIDS, MI 49544 www.meijer.com

Do not take the Daytime and Nighttime tablets at the same time.



meijer 44-453485

SINUS PE CONGESTION DAYTIME NIGHTTIME

diphenhydramine hcl, phenylephrine hcl kit

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Drod	uct	Inform	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:79481-4534

I	Packaging			
7	tem Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:79481- 4534-1	1 in 1 CARTON; Type 0: Not a Combination Product	07/05/2023	

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 PE CONGESTION DAYTIME

phenylephrine hcl tablet, film coated

Product Information		
Item Code (Source)	NDC:79481-7453	
Route of Administration	ORAL	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg		

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color red Score no score				
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	44;453	
Contains				

Packaging

# Ite	em Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC 745	::79481- 3-2	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	07/05/2023		

Part 2 of 2

SINUS PE CONGESTION NIGHTTIME

diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

Item Code (Source) NDC:79481-7485

Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYDEXTROSE (UNII: VH2XOU12IE)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
TRIACETIN (UNII: XHX3C3X673)			

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	44;485	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79481- 7485-3	8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	07/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	07/05/2023			

Labeler - Meijer Distribution, Inc. (006959555)

Establishment Name Address ID/FEI Business Operations

LNK International, Inc. 832867837 manufacture(79481-4534) , pack(79481-4534)

Establishment

Lacabilatilient			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(79481-4534)

EstablishmentNameAddressID/FEIBusiness OperationsLNK International, Inc.868734088manufacture(79481-4534)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(79481-4534)

Revised: 7/2023 Meijer Distribution, Inc.