SINUS PE CONGESTION- diphenhydramine hcl, phenylephrine hcl
Walgreen Company

Walgreens 44-453485-Sinus PE Congestion

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

DAY & NIGHT PACK

NDC 0363-4534-09

Walgreens

WALGREENS PHARMACIST RECOMMENDED†

Compare to the active ingredients in
Sudafed PE® Day + Night Sinus Congestion††

DAYTIME • NON-DROWSY **Sinus PE** **Congestion** **PHENYLEPHRINE HCl 10 mg** / NASAL DECONGESTANT Maximum Strength • Relieves sinus pressure & congestion • Pseudoephedrine free **12** TABLETS ACTUAL SIZE	**NIGHTTIME** **Sinus PE** **Congestion** **DIPHENHYDRAMINE HCl 25 mg / ANTIHISTAMINE** **PHENYLEPHRINE HCl 10 mg / NASAL DECONGESTANT** • Relieves itchy, water eyes, runny nose & itchy throat • Pseudoephedrine free **8** TABLETS ACTUAL SIZE

TOTAL 20 TABLETS

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

†Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

††This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed PE® Day + Night Sinus Congestion.

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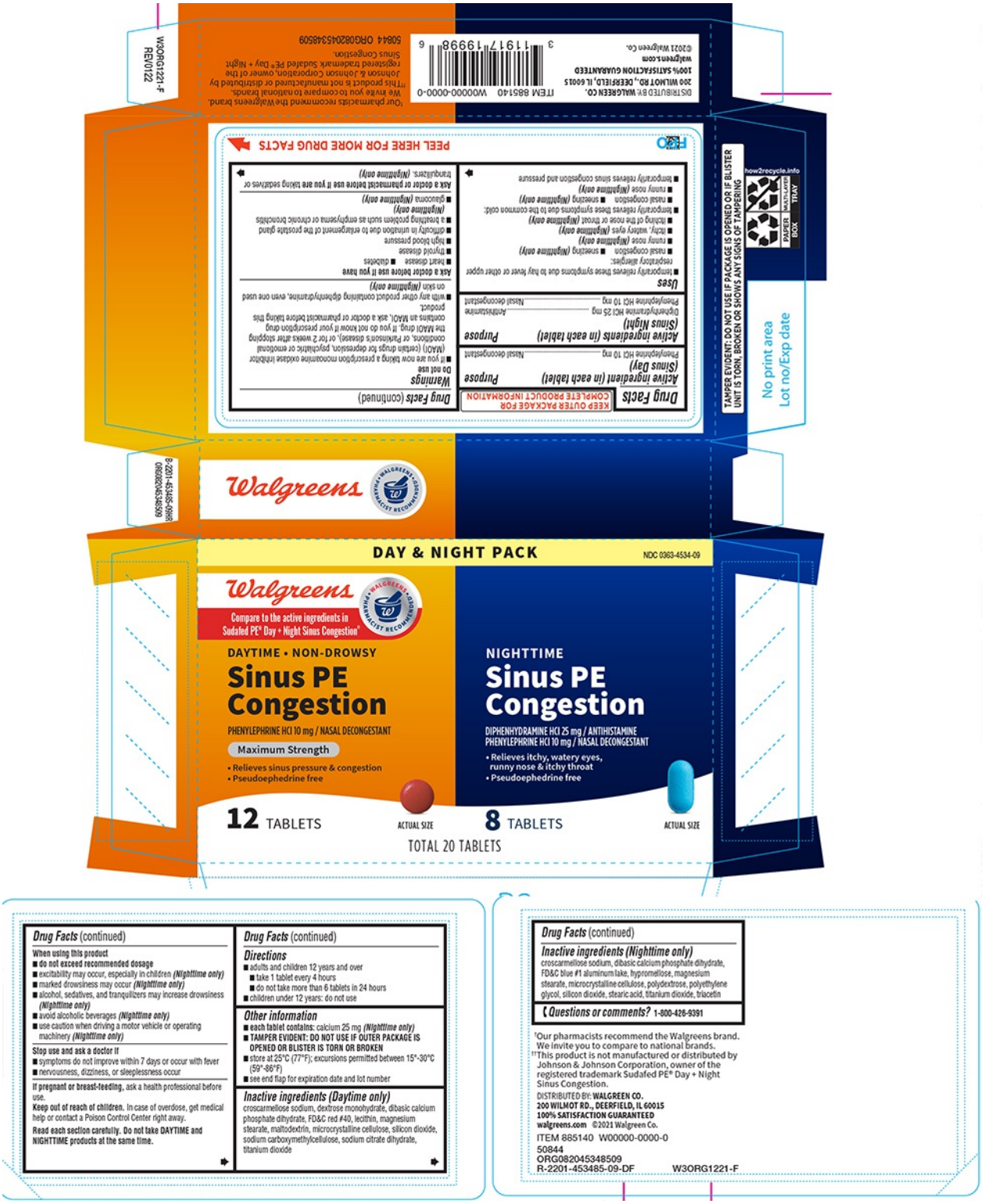
DISTRIBUTED BY: **WALGREEN CO.**
200 WILMONT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com



Walgreens 44-453485-09

SINUS PE CONGESTION

diphenhydramine hcl, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-4534

Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4534-09	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/19/2022	

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:0363-7453
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: K679OBS311)	
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				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:0363-7453-42	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	01/19/2022	

Part 2 of 2

SINUS PE CONGESTION NIGHTTIME

diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

Item Code (Source)	NDC:0363-7485
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: 3WQ0SDW1A)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-7485-40	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	01/19/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/19/2022	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-4534) , pack(0363-4534)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0363-4534)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(0363-4534)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0363-4534)

Revised: 1/2024 Walgreen Company