

**DAYTIME AND NIGHTTIME SINUS CONGESTION PE- diphenhydramine hcl,
phenylephrine hcl
CVS PHARMACY**

CVS 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

CVSHealth®

Compare to the active ingredients in Sudafed PE® Sinus Congestion Daytime and Nighttime*

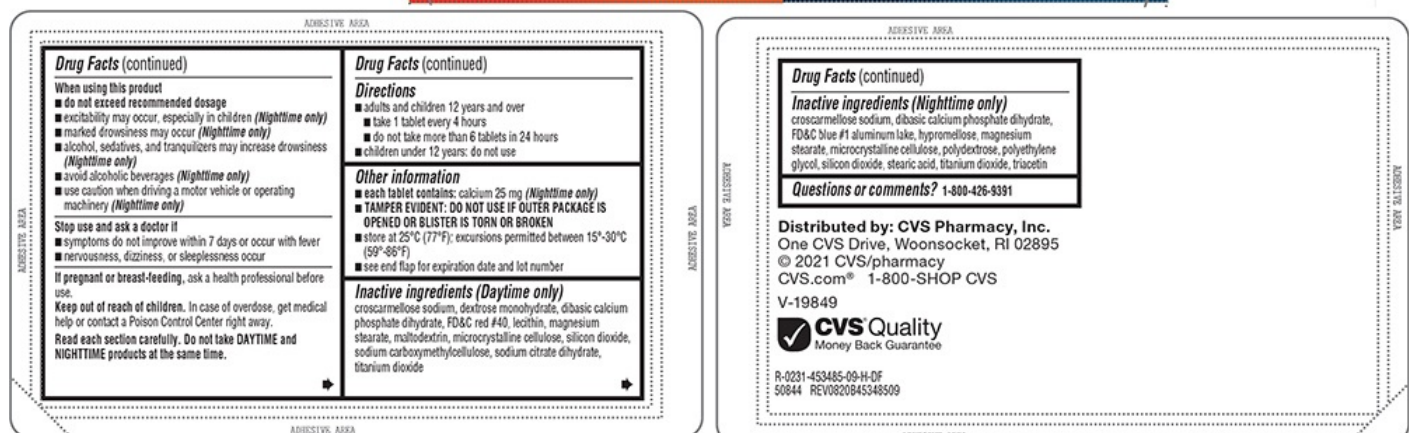
DAYTIME - Non-Drowsy Sinus Congestion PE PHENYLEPHRINE HCl Nasal decongestant Relieves: Nasal congestion Actual Size 12 TABLETS	NIGHTTIME Sinus Congestion PE DIPHENHYDRAMINE HCl Antihistamine PHENYLEPHRINE HCl Nasal decongestant Relieves: Nasal congestion Runny nose Actual Size 8 TABLETS
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20 TOTAL TABLETS

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 Johnson & Johnson Corporation, owner of the registered trademark Sudafed PE® Sinus Congestion Daytime and Nighttime.
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CVS Health 44-453485

DAYTIME AND NIGHTTIME SINUS CONGESTION PE

diphenhydramine hcl, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-938
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-938-09	1 in 1 CARTON; Type 0: Not a Combination Product	06/10/2019	

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

DAYTIME SINUS CONGESTION PE

phenylephrine hcl tablet, film coated

Product Information

Route of Administration	ORAL
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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 (UNII: 05JZI7B19X)	
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		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	01/14/2005	

Part 2 of 2

NIGHTTIME SINUS CONGESTION PE

diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

Route of Administration	ORAL
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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
CROSCARMELOSE 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: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRACETIN (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		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	08/10/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/10/2019	

Labeler - CVS PHARMACY (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(69842-938) , pack(69842-938)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(69842-938)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(69842-938)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(69842-938)

Revised: 7/2023

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