

**SINUS PRESSURE AND CONGESTION RELIEF- diphenhydramine hcl,  
phenylephrine hcl  
Rite Aid Corporation**

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**Rite Aid 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**

NDC 11822-9485-9

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

**SINUS PRESSURE & CONGESTION RELIEF PE**

<b>DAYTIME</b> <b>PHENYLEPHRINE HCl</b> NASAL DECONGESTANT <b>NON-DROWSY</b> Relieves nasal congestion ACTUAL SIZE	<b>NIGHTTIME</b> <b>DIPHENHYDRAMINE HCl</b> <b>PHENYLEPHRINE HCl</b> ANTIHISTAMINE, NASAL DECONGESTANT Relieves nasal congestion, runny nose ACTUAL SIZE
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**12 DAYTIME**  
TABLETS

**8 NIGHTTIME**  
TABLETS

**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**



## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-9485
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-9485-9	1 in 1 CARTON; Type 0: Not a Combination Product	07/02/2019	

## 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 PRESSURE AND CONGESTION RELIEF

phenylephrine hcl tablet, film coated

## Product Information

<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>TITANIUM DIOXIDE</b> (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	07/02/2019	

## Part 2 of 2

### NIGHTTIME SINUS PRESSURE AND CONGESTION RELIEF

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
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

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

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	07/02/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/02/2019	

**Labeler** - Rite Aid Corporation (014578892)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(11822-9485) , pack(11822-9485)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(11822-9485)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(11822-9485)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(11822-9485)

Revised: 7/2025

Rite Aid Corporation