# NASAL DECONGESTANT PE MAXIMUM STRENGTH- phenylephrine hcl tablet, film coated

Cardinal Health 110, LLC. DBA Leader

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Leader 44-453

## Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

### **Purpose**

Nasal decongestant

#### Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- 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.

## Ask a doctor before use if you have

- diabetes
- heart disease
- high blood pressure
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland

## When using this product

do not exceed recommended dosage.

## Stop use and ask a doctor if

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

## 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.

#### **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: ask a doctor

#### Other information

- 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

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

#### Questions or comments?

1-800-426-9391

## Principal display panel

#### **LEADER™**

NDC 70000-0126-2

Maximum Strength | Non-Drowsy

#### Nasal

### **Decongestant PE**

Phenylephrine HCl, 10 mg | Nasal Decongestant

Sinus Pressure + Congestion Pseudoephedrine-Free

**18** TABLETS

Actual size

COMPARE TO SUDAFED PE® SINUS CONGESTION active ingredient\*

100% Money Back Guarantee

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.

50844 REV0820A45323

**Cardinal**Health™

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All LEADER™ Brand Products Have A

100% Money Back Guarantee

Return to place of purchase if not satisfied.

## LEADER?

Maximum Strength | Non-Drowsy

## Nasal Decongestant PE

Phenylephrine HCI, 10 mg | Nasal Decongestant

# LEADER?

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed PE® Sinus Congestion.

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

and Expiration No.

2 to

NDC 70000-0126-1

Maximum Strength | Non-Drowsy

# Nasal Decongestant PE

Phenylephrine HCl, 10 mg | Nasal Decongestant



100% Money Back Guarantee

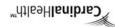




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#### Essential to Care" since 1979

www.myleader.com 1-800-200-6313 DUBLIN, OHIO 43017 DISTRIBUTED BY CARDINAL HEALTH



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B-0225-453-44 REV0820A45344

#### Questions or comments? 1-800-426-9391

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

- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C
  - OPENED OR BLISTER IS TORN OR BROKEN ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS Other information
- children under 12 years: ask a doctor hours. Do not take more than 6 tablets in 24 hours. ■ adults and children 12 years and over: take 1 tablet every 4 Directions

help or contact a Poison Control Center right away. Keep out of reach of children. In case of overdose, get medical

If pregnant or breast-feeding, ask a health professional before **Drug Facts** (continued)

■ symptoms do not improve within 7 days or occur with fever ■ nervousness, dizziness, or sleeplessness occur Stop use and ask a doctor if

- When using this product do not exceed recommended dosage. ■ difficulty in urination due to enlargement of the prostate gland
  - thyroid disease high blood pressure
    - sətə dsib 🔳 ■ heart disease
    - Ask a doctor before use if you have

before taking this product. prescription drug contains an MAOI, ask a doctor or pharmacist after stopping the MAOI drug. If you do not know if your or emotional conditions, or Parkinson's disease), or for 2 weeks oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric Do not use if you are now taking a prescription monoamine *Sprinibly* 

#### hay fever or other upper respiratory allergies

- temporarily relieves nasal congestion due to the common cold,
  - temporarily relieves sinus congestion and pressure

Nasal decongestant

Purpose

Active ingredient (in each tablet) Drug Facts

Phenylephrine HCI 10 mg

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Important: Read all product information before using.

44-453

## NASAL DECONGESTANT PE MAXIMUM STRENGTH

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0126
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	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				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:70000- 0126-1	1 in 1 CARTON	01/14/2005			
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:70000- 0126-2	3 in 1 CARTON	01/14/2005			
2		24 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	

## Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0126) , pack(70000-0126)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(70000-0126)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(70000-0126)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(70000-0126)

Revised: 4/2024 Cardinal Health 110, LLC. DBA Leader