

**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°C-30°C (59°F-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 70000-0126-1

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

**CardinalHealth™**

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

**Essential to Care™ since 1979**

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All LEADER™ Brand Products Have A

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.

LEADER<sup>TM</sup>

Maximum Strength | Non-Drowsy  
**Nasal Decongestant PE**

Phenylephrine HCl, 10 mg | Nasal Decongestant

LEADER<sup>TM</sup>

NDC 70000-0126-1

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<sup>®</sup> SINUS CONGESTION**  
 active ingredient\*

100% Money Back Guarantee

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed PE<sup>®</sup> Sinus Congestion.  
 50844 REV0820A45344

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

No Print/No Varnish  
 Lot and Expiration No.

0 96295 12949 6  
 CIN 5285275  
 REV. 3/21

All LEADER<sup>TM</sup> Brand Products Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied.

B-0225-453-44  
 REV0820A45344

DISTRIBUTED BY CARDINAL HEALTH  
 DUBLIN, OHIO 43017  
 www.myladder.com 1-800-200-6315  
 Essential to Care<sup>™</sup> since 1979  
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|--|--|
| <p><b>Drug Facts</b><br/>                 Active ingredient (in each tablet) Phenylephrine HCl 10 mg ..... Nasal decongestant</p>  | <p><b>Uses</b><br/>                 ■ temporarily relieves sinus congestion and pressure<br/>                 ■ temporarily relieves nasal congestion due to the common cold,<br/>                 hay fever or other upper respiratory allergies</p>  |
| <p><b>Warnings</b><br/>                 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.</p> | <p><b>Ask a doctor before use if you have</b><br/>                 ■ heart disease ■ diabetes<br/>                 ■ thyroid disease ■ high blood pressure<br/>                 ■ difficulty in urination due to enlargement of the prostate gland</p>   |
| <p><b>When using this product do not exceed recommended dosage.</b><br/>                 ■ difficulty in urination due to enlargement of the prostate gland<br/>                 ■ thyroid disease ■ high blood pressure<br/>                 ■ heart disease ■ diabetes</p>   | <p><b>Stop use and ask a doctor if</b><br/>                 ■ nervousness, dizziness, or sleeplessness occur<br/>                 ■ symptoms do not improve within 7 days or occur with fever</p>  |
| <p><b>Other information</b><br/>                 ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN<br/>                 ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)<br/>                 ■ see end flap for expiration date and lot number</p>   | <p><b>Inactive ingredients</b> croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&amp;C red #40, lecithin, magnesium stearate, methocel K100, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide</p> |
| <p><b>Directions</b><br/>                 ■ adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.<br/>                 ■ children under 12 years: ask a doctor</p>  | <p><b>Questions or comments?</b> 1-800-426-9391</p>  |
| <p><b>Drug Facts (continued)</b><br/>                 If pregnant or breast-feeding, ask a health professional before use.<br/>                 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>  |  |

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION Important: Read all product information before using.

44-453

**NASAL DECONGESTANT PE MAXIMUM STRENGTH**

phenylephrine hcl tablet, film coated

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

| <b>Ingredient Name</b>   | <b>Strength</b> |
|--|-----------------|
| <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

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | red   | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND | <b>Size</b>         | 7mm      |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | 44;453   |
| <b>Contains</b> |       |                     |          |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                              | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:70000-0126-1 | 1 in 1 CARTON   | 01/14/2005                  | 03/31/2026                |
| 1        |                  | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product |                             |                           |
| 2        | NDC:70000-0126-2 | 3 in 1 CARTON   | 01/14/2005                  | 03/31/2026                |
| 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           | 03/31/2026         |

**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    | Business Operations     |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. |         | 832867894 | manufacture(70000-0126) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations     |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. |         | 868734088 | manufacture(70000-0126) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations     |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. |         | 117025878 | manufacture(70000-0126) |

Revised: 10/2025

Cardinal Health 110, LLC. DBA Leader