

**LEADER 12 HOUR SINUS NASAL DECONGESTANT- pseudoephedrine hcl tablet, film coated, extended release  
Cardinal Health 110, LLC. dba Leader**

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**Cardinal Health 12-Hour Sinus Nasal Decongestant Drug Facts**

**Active ingredient (in each tablet)**

Pseudoephedrine HCl 120 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**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged 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 a 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 (1-800-222-1222).

### Directions

|                                       |  |
|---------------------------------------|--|
| adults and children 12 years and over | <ul style="list-style-type: none"><li>take 1 tablet every 12 hours</li><li>do not take more than 2 tablets in 24 hours</li></ul> |
| children under 12 years               | do not use this product in children under 12 years of age  |

### Other information

- each tablet contains:** calcium 45 mg
- store at 20-25°C (68-77°F) in a dry place
- protect from light
- do not use if blister unit is broken or torn**
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP *Drug Release Test 3*

### Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

### Questions or comments?

**1-800-719-9260**

### Principal Display Panel

LEADER™

Maximum Strength | Non-Drowsy

12-Hour Sinus Nasal Decongestant

Pseudoephedrine Hydrochloride Extended Release Tablets, 120 mg

Nasal Decongestant

Sinus Pressure + Congestion

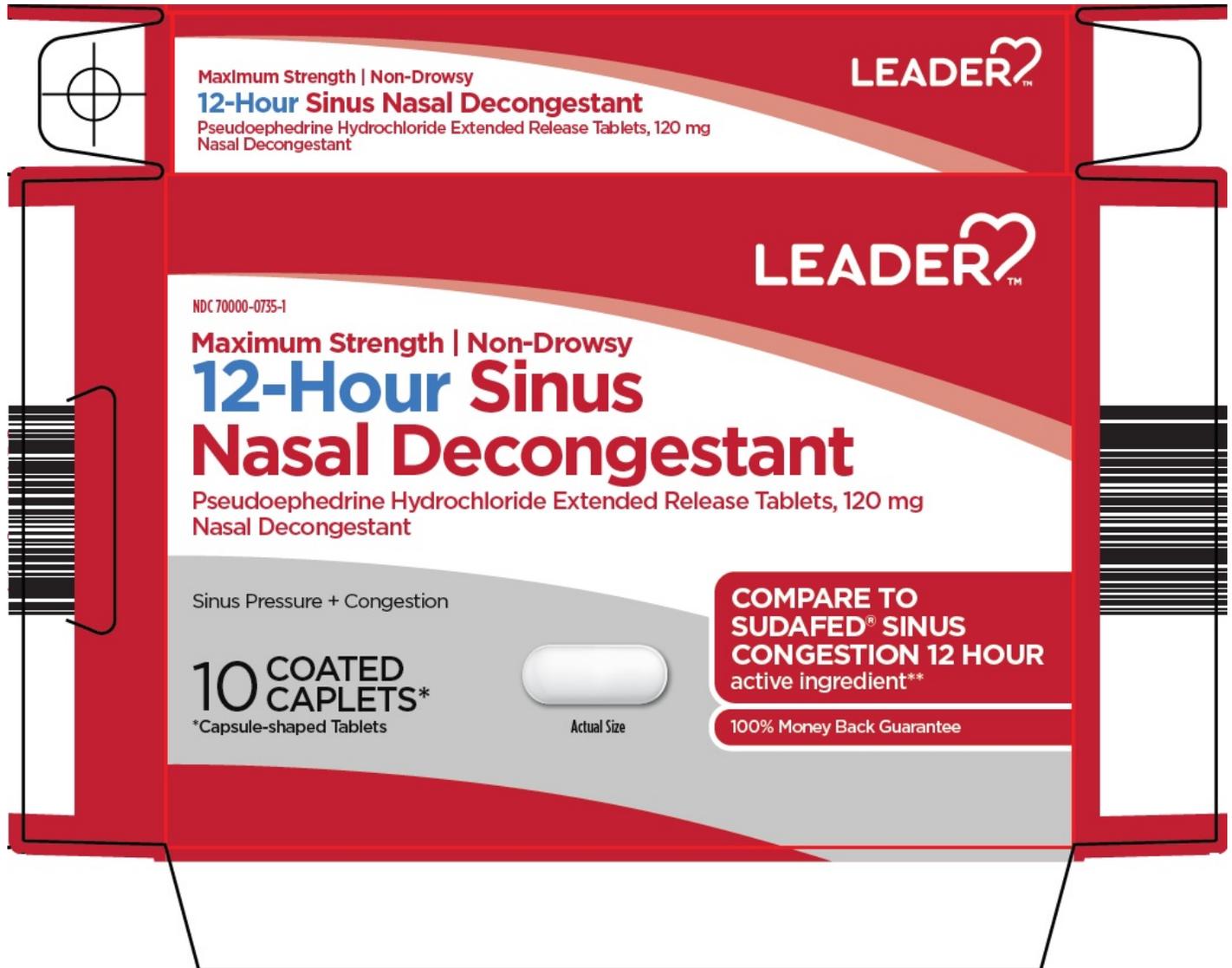
10 COATED CAPLETS\*

\*Capsule-shaped Tablets

Actual Size

COMPARE TO SUDAFED® SINUS CONGESTION 12 HOUR active ingredient

100% Money Back Guarantee



05452 E9 C11

CODE AREA

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**Drug Facts (continued)****Directions**

- |                                       |   |
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\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc., distributor of Sudafed® Sinus Congestion 12 Hour.

Return to place of purchase if not satisfied.  
**100% Money Back Guarantee**  
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DUBLIN, OHIO 43017  
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Essential to Care™ since 1979

**LEADER 12 HOUR SINUS NASAL DECONGESTANT**

pseudoephedrine hcl tablet, film coated, extended release

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70000-0735 |
| <b>Route of Administration</b> | ORAL           |                           |                |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength                | Strength |
|---|----------------------------------|----------|
| <b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N)<br>(PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F) | PSEUDOEPHEDRINE<br>HYDROCHLORIDE | 120 mg   |

**Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                        |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                     |          |
| <b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP) |          |
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)           |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)          |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)    |          |

**POLYSORBATE 80** (UNII: 6OZP39ZG8H)

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

### Product Characteristics

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | WHITE | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL  | <b>Size</b>         | 18mm     |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | L054     |
| <b>Contains</b> |       |                     |          |

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0735-1 | 10 in 1 CARTON   | 08/07/2025           |                    |
| 1 |                  | 1 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 |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA075153                               | 08/07/2025           |                    |

**Labeler** - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 8/2025

Cardinal Health 110, LLC. dba Leader