

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

Cardinal Health 12 Hour 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">• take 1 tablet every 12 hours• do not take more than 2 tablets in 24 hours
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

Maximum Strength | Non-Drowsy

12-Hour Nasal Decongestant

Pseudoephedrine Hydrochloride Extended-Release Tablets, 120 mg

Nasal Decongestant | Sinus

COMPARE TO SUDAFED® SINUS CONGESTION 12 HOUR MAXIMUM STRENGTH active ingredient

Sinus Pressure + Congestion

10 COATED CAPLETS*

*Capsule-shaped Tablets

Actual Size

100% Money Back Guarantee

Maximum Strength | Non-Drowsy
12-Hour Nasal Decongestant
 Pseudoephedrine Hydrochloride Extended-Release Tablets, 120 mg
 Nasal Decongestant | Sinus



NDC 70000-0475-1

Maximum Strength | Non-Drowsy
12-Hour Nasal Decongestant

Pseudoephedrine Hydrochloride Extended-Release Tablets, 120 mg
 Nasal Decongestant | Sinus

Sinus Pressure + Congestion

10 COATED CAPLETS*

*Capsule-shaped Tablets



Actual Size

COMPARE TO SUDAFED® SINUS CONGESTION 12 HOUR MAXIMUM STRENGTH active ingredient**

100% Money Back Guarantee

CODE AREA

05452 E9 C 10

CIN 5502273 REV. 2/20



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✓ All LEADER™ Brand Products Have A 100% Money Back Guarantee
 Return to place of purchase if not satisfied.

Drug Facts

Active ingredient (in each tablet) Purpose
 Pseudoephedrine HCl 120 mg. Nasal decongestant

Uses

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- temporarily relieves sinus congestion and pressure

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Drug Facts (continued)

Directions

- | | |
|---------------------------------------|---|
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Questions or comments? 1-800-719-9260

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

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LEADER 12 HOUR NASAL DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0475
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	L054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0475-1	10 in 1 CARTON	02/11/2019	
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	02/11/2019	

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

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader