

12 HOUR NASAL DECONGESTANT- pseudoephedrine hydrochloride tablet, film coated
CARDINAL HEALTH

Pseudoephedrine hydrochloride

Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl, USP 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

- store at 59° to 77° F in a dry place. Protect from light
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

Inactive ingredients

castor oil, colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, titanium dioxide

Questions?

call **1-800-406-7984**

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

LEADER™

NDC 70000-0656-1

Maximum Strength | Non-Drowsy

12-Hour

Nasal Decongestant

Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 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

5249222

Expiration Date:

Batch No.:

NON VARNISH

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Pseudoephedrine HCl USP 120 mg.....Nasal decongestant

Uses
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temporarily relieves sinus congestion and pressure

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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

Drug Facts (continued)

Purpose
Stop use and ask a doctor if
■ symptoms do not improve within 7 days or occur with a fever
■ nervousness, dizziness, or sleeplessness occur
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5249222

LEADERTM

Maximum Strength | Non-Drowsy
12-Hour Nasal Decongestant

Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 120 mg
Nasal Decongestant

LEADERTM

NDC 70000-0656-1

Maximum Strength | Non-Drowsy
12-Hour Nasal Decongestant

Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 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

CardinalHealthTM

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to CareTM since 1979

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**This product is not affiliated with the makers/owners of Sudafed[®] Sinus Congestion 12 Hour.

Keep the carton. It contains important information. See end panel for expiration date. Return to place of purchase.



CIN 5874565 REV. 11/23



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

LEADERTM

12 HOUR NASAL DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0656
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
CASTOR OIL (UNII: D5340Y2I9G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	204
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0656-1	1 in 1 CARTON	05/16/2024	
1		10 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	ANDA077442	05/16/2024	

Labeler - CARDINAL HEALTH (063997360)

Registrant - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(70000-0656)

Revised: 5/2024

CARDINAL HEALTH