

PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, extended release

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

- 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
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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, microcrystalline cellulose, magnesium stearate, titanium dioxide

Questions?

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

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

NDC 70000-0164-1

LEADER™

NON-DROWSY | MAXIMUM STRENGTH

12 Hour Nasal Decongestant

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

12 Hour

SINUS PRESSURE + CONGESTION

COMPARE TO
SUDAFED® 12 HOUR
active ingredient*

100% Money
Back Guarantee

10 COATED CAPSULE-SHAPED TABLETS 120 mg EACH

5195186

Expiration Date:

Batch No.

NON VARNISH

Drug Facts

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

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

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

Drug Facts (continued)

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

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 ■ take 1 tablet every 12 hours in 12 years and over ■ 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.

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

Questions? call 1-800-406-7984



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



NON-DROWSY | MAXIMUM STRENGTH
12 Hour Nasal Decongestant
 Pseudoephedrine Hydrochloride, 120 mg | Long-Acting Nasal Decongestant
 Extended-Release Tablets, USP

12 Hour
 SINUS PRESSURE + CONGESTION

COMPARE TO
 SUDAFED® 12 HOUR
 active ingredient*

100% Money
 Back Guarantee

10 COATED CAPSULE-SHAPED TABLETS 120 mg EACH



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CardinalHealth™
 DISTRIBUTED BY CARDINAL HEALTH
 DUBLIN, OHIO 43007
 www.myleader.com 1-800-200-6338
 Essential to Care™ since 1979

Keep the carton. It contains important information. See end panel for expiration date.

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

CIN 5294269 REV. 03/19



PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0164
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CASTOR OIL (UNII: D5340Y2I9G)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	204
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0164-1	10 in 1 CARTON; Type 0: Not a Combination Product	02/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077442	02/15/2017	

Labeler - Cardinal Health (097537435)

Registrant - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 3/2019

Cardinal Health