

**PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet
CARDINAL HEALTH 110, LLC DBA LEADER**

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
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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 70000-0601-1

LEADER™

Maximum Strength | Non-Drowsy

Pseudoephedrine

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

12 Hour

Sinus Pressure + Congestion

COMPARE TO
SUDAFED® 12 HOUR
active ingredient

100% Money Back Guarantee

20 COATED CAPSULE
SHAPED TABLETS

5230676

5230676

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Pseudoephedrine HCl, USP 120 mg.....Nasal decongestant</p> <p>Purpose</p> <p>temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies</p> <p>Warnings</p> <p>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>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease high blood pressure thyroid disease diabetes trouble urinating due to an enlarged prostate gland <p>When using this product do not exceed recommended dosage</p>	
<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> symptoms do not improve within 7 days or occur with a fever nervousness, dizziness, or sleeplessness occur <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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)</p> <p>Directions</p> <p>adults and children ■ take 1 tablet every 12 hours</p> <p>children under 12 years ■ do not take more than 2 tablets in 24 hours</p> <p>do not use this product in children under 12 years of age</p> <p>Other information</p> <p>store at 59° to 77° F in a dry place. Protect from light</p> <p>■ TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.</p> <p>Inactive ingredients</p> <p>cellulose, magnesium stearate, titanium dioxide, castor oil, colloidal silicon dioxide, hypromellose, microcrystalline cellulose</p> <p>Questions? call 1-800-406-7984</p>	

LEADER²

Maximum Strength | Non-Drowsy

Pseudoephedrine

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

LEADER²

Maximum Strength | Non-Drowsy

Pseudoephedrine

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

12-Hour
Sinus Pressure + Congestion

20 COATED CAPSULE SHAPED TABLETS



Actual Size

COMPARE TO SUDAFED[®] 12 HOUR active ingredient*

100% Money Back Guarantee

Expiration Date: _____

Batch No. _____

NON-VARNISH

DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OH 43017
www.leader.com
1-800-200-6363
Essential to Care[™] since 1979



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CIN 5777354 REV. 4/22



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*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Sudafed[®] 12 Hour.

100% Money Back Guarantee
Return to place of purchase.

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

PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0601
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:70000-0601-1	1 in 1 CARTON	03/09/2022	
1		20 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	03/09/2022	

Labeler - CARDINAL HEALTH 110, LLC DBA LEADER (063997360)

Registrant - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories		184769029	MANUFACTURE(70000-0601)

Revised: 5/2022

CARDINAL HEALTH 110, LLC DBA LEADER