# PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated, extended release

Chain Drug Marketing Association Inc.

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### 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 do not use this product in children 12 years 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, microcrystalline cellulose, magnesium stearate, titanium dioxide

#### Questions?

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

Distributed by C.D.M.A., Inc.© 43157 W. Nine Mile Novi, MI 48376-0995

## PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

 $QC_{\mathbb{R}}$  QUALITY CHOICE

NDC 63868-143-10

\*Compare to Active Ingredient in SUDAFED® 12 Hour

MAXIMUM STRENGTH | NON-DROWSY

Nasal Decongestant 12 Hour

Pseudoephedrine Hydrochloride 120 mg Extended-Release Tablets, USP

Long-Acting Nasal Decongestant

SINUS PRESSURE + CONGESTION

10 Coated Capsule-Shaped Tablets 120 mg Each

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Drug Facts (continued)



# **Nasal Decongestant 12 Hour**

Pseudoephedrine Hydrochloride 120 mg Extended-Release Tablets, USP

NDC 63868-143-10

\*Compare to Active ingredient in SUDAFED® 12 Hour



## MAXIMUM STRENGTH | NON-DROWSY

# Nasal Decongestant 12 Hour

Pseudoephedrine Hydrochloride 120 mg **Extended-Release Tablets, USP** 

**Long-Acting Nasal Decongestant** 

SINUS PRESSURE + CONGESTION



# 10 Coated Capsule-Shaped Tablets 120 mg Each



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

\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Sudafed® 12 Hour.







Pseudoephedrine Hydrochloride 120 mg Extended-Release Tablets, USP Nasal Decongestant 12 pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-143
Route of Administration	ORAL		

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	$ \textbf{PSEUDO EPHEDRINE HYDRO CHLO RIDE} \ (UNII: 6V9V2RYJ8N) \ (PSEUDO EPHEDRINE - UNII: 7CUC9DDI9F) $	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CASTOR OIL (UNII: D5340 Y2I9 G)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				
MAGNESIUM STEARATE (UNII: 70097M6130)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

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

l	P	ackaging			
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1	NDC:63868-143-10	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/28/2006	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077442	04/28/2006		

# Labeler - Chain Drug Marketing Association Inc. (011920774)

# Registrant - Ohm Laboratories Inc. (184769029)

Establishment			
Name	Address	ID/FEI	Business Operations

Ohm Laboratories Inc. 051565745 manufacture(63868-143)

Revised: 3/2019 Chain Drug Marketing Association Inc.