# PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated, extended release Publix Super Markets Inc

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
- thvroid 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	do not use this product in children under
years	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 PUBLIX SUPER MARKETS, INC., 3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811

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

NDC 56062-204-21

NON-DROWSY nasaldecongestant

PSEUDOEPHEDRINE HYDROCHLORIDE 120 mg 12-HOUR EXTENDED-RELEASE TABLETS, USP LONG-ACTING NASAL DECONGESTANT

- SINUS PRESSURE + CONGESTION
- MAXIMUM STRENGTH

20 COATED CAPSULE-SHAPED TABLETS 120 mg EACH

**ACTUAL SIZE** 

\*Compare to the active ingredient in Sudafed® 12 Hour

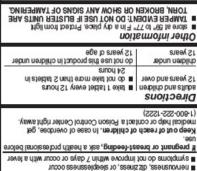
#### Questions? call 1-800-406-7984 castor oil, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, magnesium stearate, titarium dioxide When using this product do not exceed recommended pureif ejesead pefisejue ur oj enp flugraun ejanaj ... Inactive ingredients enueserq boold right esseelb heert esseelb biorynt esseelb esseelb biorynt esseelb esseelb biorynt esseelb esseelb biorynt esseelb Ask a doctor before use if you have

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■ femporarily relieves sinus congestion and pressure cold, hay fever or other upper respiratory allergies I temporarily refeves nasal congestion due to the common

Pseudoephedrine HCI, USP 120 mg. (in each tablet) Purpose Active ingredient

Drug Facts



Stop use and ask a doctor if Drug Facts (continued)



# **NON-DROWSY** nasaldecongestant

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PSEUDOEPHEDRINE HYDROCHLORIDE 120 mg 12-HOUR EXTENDED-RELEASE TABLETS, USP/LONG-ACTING NASAL DECONGESTANT





NDC 56062-204-21

NON-DROWSY

# nasaldecongestant

PSEUDOEPHEDRINE HYDROCHLORIDE 120 mg 12-HOUR EXTENDED-RELEASE TABLETS, USP LONG-ACTING NASAL DECONGESTANT

- SINUS PRESSURE + CONGESTION
- MAXIMUM STRENGTH



\*Compare to the active ingredient in Sudafed® 12 Hour

COATED CAPSULE-SHAPED TABLETS 120 mg EACH

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

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

DISTRIBUTED BY

PUBLIX SUPER MARKETS, INC., 3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811 publix.com

1-888-267-3037

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# Publix.

#### PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-204
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>PSEUDO EPHEDRINE HYDRO CHLO RIDE</b> (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients			
Ingredient Name	Strength		
CASTOR OIL (UNII: D5340 Y219 G)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

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

P	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:56062-204-21	20 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 - Publix Super Markets Inc (006922009)

# Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		184769029	manufacture(56062-204)	

Revised: 3/2019 Publix Super Markets Inc