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

**Drug Facts** 

#### ACTIVE INGREDIENT (IN EACH TABLET)

Pseudoephedrine HCl USP, 120 mg

#### **PURPOSE**

Nasal decongestant

#### **USES**

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- 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
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland

#### When using this product

do not use more than directed

#### Stop use and ask a doctor if

- symptoms do not get better within 7 days or occur with a fever
- you get nervous, dizzy, or sleepless

#### 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.

#### **DIRECTIONS**

- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

#### 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

#### PRINCIPAL DISPLAY PANEL

**Publix** 

**NON-DROWSY** 

nasal decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE

120 mg EXTENDED-RELEASE TABLETS, USP

#### 12 HOUR LONG-ACTING NASAL DECONGESTANT

- nasal & sinus congestion due to colds & allergies
- sinus pressure
- maximum strength

#### 20 COATED CAPSULE-SHAPED TABLETS 120 mg EACH

\*\*Compare to Active Ingredient in Sudafed® 12 Hour

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.

5089482/R1011



- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose
  - upper respiratory allergies ш һау fever
    - common cold

USES temporarily relieves nasal congestion due to:

..Nasal decongestant seudoephedrine HCI USP, 120 mg.. (in each tablet)

Active ingredient

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

- protect from light
- store at 59° to 77° F in a dry place Other information
- 1 tablet every 12 hours; not more than 2 tablets in 24 hours children under 12 years: aak a doctor adults and children 12 years and older:

Directions

medical help or contact a Poison Control Center right away. Keep out of reach of children. In case of overdose, get

- If pregnant or breast-feeding, ask a health professional
- you get nervous, dizzy, or sleepless ■ symptoms do not get better within 7 days or occur with a fever Stop use and ask a doctor if

When using this product ■ do not use more than directed ■ trouble urinating due to an enlarged prostate gland

Drug Facts (continued)





NON-DROWSY

## nasaldecongestant

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

Purpose





**NON-DROWSY** 

## nasaldecongestant

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

- nasal & sinus congestion due to colds & allergies
- · sinus pressure
- · maximum strength

20 COATED CAPSULE-SHAPED TABLETS 120 mg EACH



impare to Active Ingredient in Sudafed® 12 Hour

11019

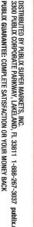
See end panel for expiration date. It contains important information. Keep the carton.

"This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark SUDAFED® 12 Hour.

#### PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated, extended release





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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (PSEUDO EPHEDRINE)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CASTOR OIL				
COLLO IDAL SILICON DIO XIDE				
HYPROMELLOSES				
CELLULO SE, MICRO CRYSTALLINE				
MAGNESIUM STEARATE				
TITANIUM DIO XIDE				

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

]	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-204-21	20 in 1 BLISTER PACK		

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: 1/2013 Publix Super Markets Inc