

# **SHOPRITE NASAL DECONGESTANT- pseudoephedrine hcl tablet, film coated, extended release**

**Wakefern Food Corporation**

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## **ShopRite Nasal Decongestant Drug Facts**

### **Active ingredient (in each tablet)**

Pseudoephedrine HCl 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"><li>• take 1 tablet every 12 hours</li><li>• do not take more than 2 tablets in 24 hours</li></ul>
children under 12 years	do not use this product in children under 12 years of age

## Other information

- each tablet contains: calcium 45 mg
- store at 20-25°C (68-77°F) in a dry place
- protect from light
- do not use if blister unit is broken or torn
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP Drug Release Test 3

## Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

## Questions or comments?

1-800-SHOPRITE

## Principal Display Panel

Compare to: Active Ingredient in Sudafed® 12 Hour Caplets

MAXIMUM STRENGTH

NASAL DECONGESTANT

Pseudoephedrine Hydrochloride Extended Release Tablets, 120 mg

Long-Acting Nasal Decongestant

SINUS PRESSURE – CONGESTION

12 Hour

Non-Drowsy / Sinus / Pseudoephedrine HCl

actual size

10 COATED CAPLETS\*

\*(capsule shaped tablets, 120 mg Each)

U.S. Patent No. 5,895,663

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare  
Division of McNeil-PPC, Inc., distributor of Sudafed® 12 Hour Caplets.



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



**MAXIMUM STRENGTH**

# NASAL DECONGESTANT

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

**SINUS PRESSURE • CONGESTION**

**—12 Hour**

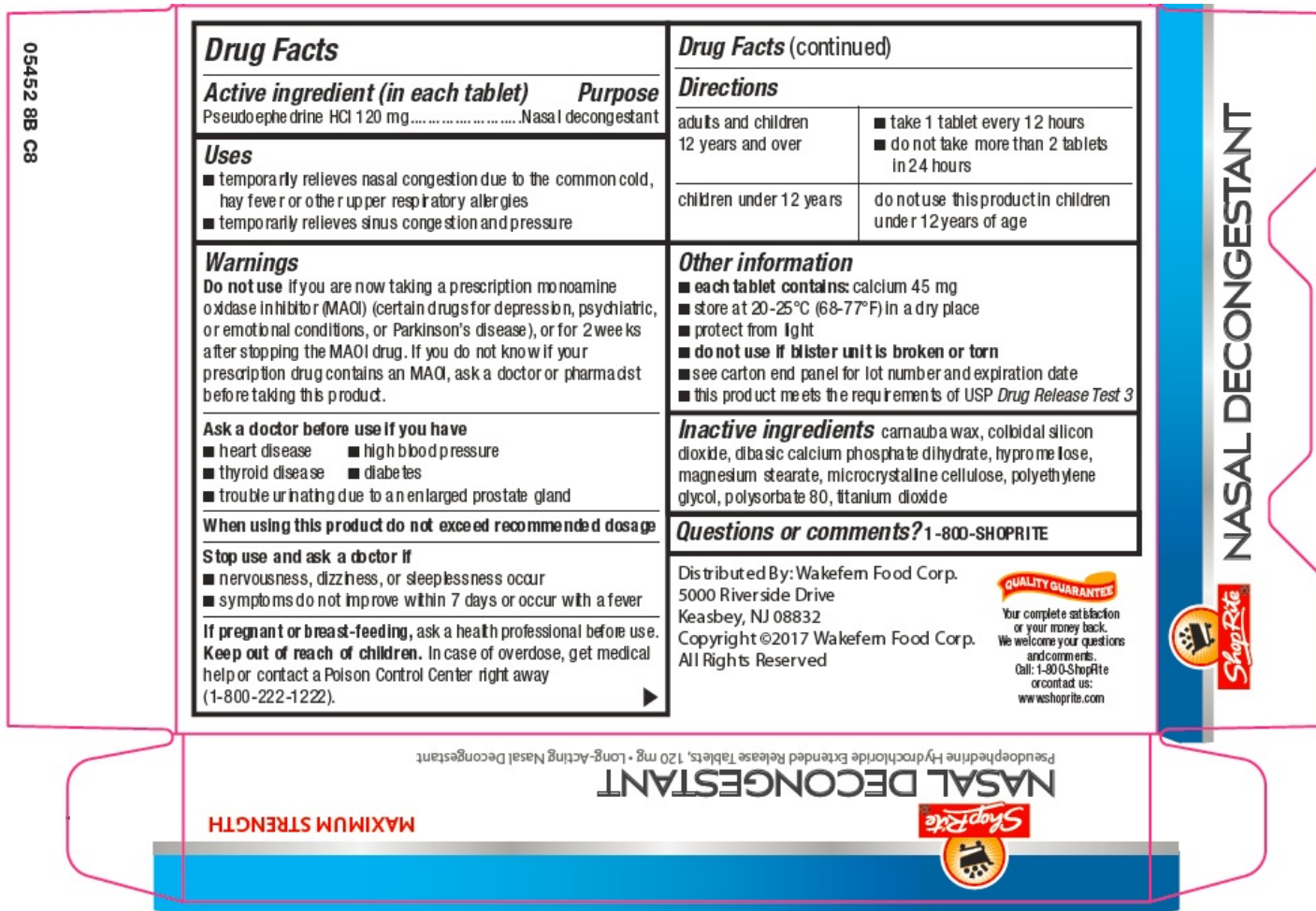
Non-Drowsy / Sinus / Pseudoephedrine HCl



actual  
size

**10**  
**COATED**  
**CAPLETS\***

\*(capsule shaped tablets,  
120 mg Each)



## SHOPRITE NASAL DECONGESTANT

pseudoephedrine hcl tablet, film coated, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-054
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)				
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)				
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
<b>Color</b>	WHITE	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm	
<b>Flavor</b>		<b>Imprint Code</b>	L054	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:41190-054-52	10 in 1 CARTON	03/25/2014	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA075153	03/25/2014		

**Labeler** - Wakefern Food Corporation (069722418)

Revised: 12/2019

Wakefern Food Corporation