# SHOPRITE NASAL DECONGESTANT- pseudoephedrine hcl tablet, film coated Wakefern Food Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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### ShopRite Nasal Decongestant Drug Facts

#### Active ingredient (in each tablet)

Pseudoephedrine HCl 30 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> <li>take 2 tablets every 4 to 6 hours</li> <li>do not take more than 8 tablets in 24 hours</li> </ul>
children ages 6 to 11 years	<ul> <li>take 1 tablet every 4 to 6 hours</li> <li>do not take more than 4 tablets in 24 hours</li> </ul>
children under 6 years	do not use this product in children under 6 years of age

## Other information

- each tablet contains: calcium 20 mg
- store at 20°-25°C (68°-77°F)
- do not use if blister unit is broken or torn

## **Inactive ingredients**

carnauba wax, dibasic calcium phosphate dihydrate, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, silicon dioxide, titanium dioxide

## Questions or comments?

1-800-SHOPRITE

## **Principal Display Panel**

Compare to: Active Ingredient in Sudafed<sup>®</sup> Congestion Tablets MAXIMUM STRENGTH NASAL DECONGESTANT Pseudoephedrine HCl Tablets, 30 mg SINUS PRESSURE + CONGESTION Non-Drowsy Nasal & Sinus Congestion actual size 48 TABLETS



#### SHOPRITE NASAL DECONGESTANT pseudoephedrine hcl tablet, film coated **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:41190-432 ORAL **Route of Administration Active Ingredient/Active Moiety Basis of Strength** Strength **Ingredient Name** PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8N) (PSEUDO EPHEDRINE PSEUDO EPHEDRINE 30 mg - UNII:7CUC9DDI9F) **HYDROCHLORIDE Inactive Ingredients** Strength **Ingredient Name** CARNAUBA WAX (UNII: R12CBM0EIZ) DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) MAGNESIUM STEARATE (UNII: 70097M6I30) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) POLYSORBATE 80 (UNII: 6OZP39ZG8H) SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) TITANIUM DIO XIDE (UNII: 15FIX9V2JP) FD&C RED NO. 40 (UNII: WZB9127XOA) **Product Characteristics** Color RED Score no score Shape ROUND (convex) Size 7mm L432 Flavor Imprint Code Contains Packaging # Item Code **Package Description** Marketing Start Date Marketing End Date 1 NDC:41190-432-67 2 in 1 CARTON 09/17/2013 1 24 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 09/17/2013 OTC monograph final part341

Labeler - Wakefern Food Corporation (069722418)

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