

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

**Shopko Stores Operating Co., LLC**

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**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

## **QUESTIONS?**

Call **1-800-406-7984**

## **PRINCIPAL DISPLAY PANEL**

**SHOPKO®**

**Compare to the active ingredient of SUDAFED® 12 Hour**

**12 Hour, Non-Drowsy**

**Nasal Decongestant**

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

**Long-Acting Nasal Decongestant**

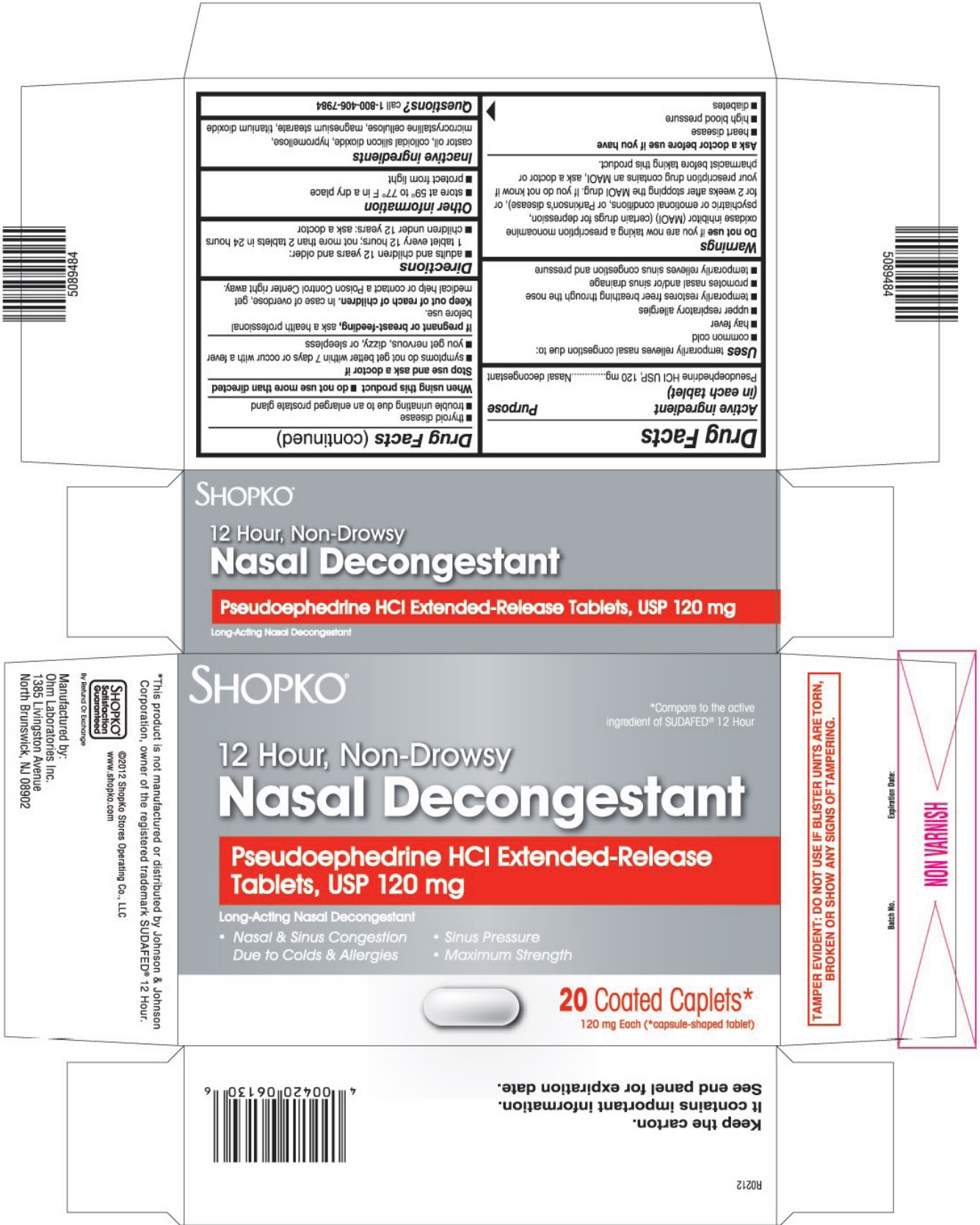
**Nasal & Sinus Congestion Due to Colds & Allergies**

**Sinus Pressure**

**Maximum Strength**

**Manufactured by: Ohm Laboratories Inc.**

**5089484/R0212**



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\*Compare to the active ingredient of SUDAFED® 12 Hour

- Nasal & Sinus Congestion Due to Colds & Allergies
- Sinus Pressure
- Maximum Strength

**20 Coated Caplets\***  
 120 mg Each (\*capsule-shaped tablet)

Manufactured by:  
 Omm Laboratories Inc.  
 1385 Livingston Avenue  
 North Brunswick, NJ 08902

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 www.shopko.com

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

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

Expiration Date: \_\_\_\_\_

Batch No. \_\_\_\_\_

**NON VARNISH**

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

R0212

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**PSEUDOEPHEDRINE HYDROCHLORIDE**  
 pseudoephedrine hydrochloride tablet, film coated, extended release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37012-204
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CASTOR OIL (UNII: D5340Y2I9G)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	204
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-204-20	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** - Shopko Stores Operating Co., LLC (023252638)**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(37012-204)

