

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

**Ohm Laboratories Inc.**

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**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
- 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

- take 1 tablet every 12 hours
- do not take more than 2 tablets in 24 hours

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children under 12 years	do not use this product in children under 12 years of age
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**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:  
Ohm Laboratories Inc.  
New Brunswick, NJ 08901

**PRINCIPAL DISPLAY PANEL - 20 Tablet Blister Pack**

†Compare To  
the active ingredient of  
Sudafed® 12 Hour.

NDC 51660-492-21

ohm®  
NON-DROWSY

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

5198328

Questions? call 1-800-406-7984

**When using this product do not exceed recommended dosage**

■ trouble urinating due to an enlarged prostate gland  
 ■ thyroid disease ■ diabetes  
 ■ heart disease ■ high blood pressure

**Ask a doctor before use if you have**

pharmacist before taking this product.

your prescription drug contains an MAOI, ask a doctor or

for 2 weeks after stopping the MAOI drug. If you do not know if

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oxidase inhibitor (MAOI) (certain drugs for depression,

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**Active ingredient**

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**(in each tablet)**

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children under 12 years	■ do not take more than 2 tablets in 24 hours
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castor oil, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, magnesium stearate, titanium dioxide

**Drug Facts (continued)**

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■ symptoms do not improve within 7 days or occur with a fever  
 ■ nervousness, dizziness, or sleeplessness occur  
 use.

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If pregnant or breast-feeding, ask a health professional before use.

5198328

NON-DROWSY

**ohm**

# Pseudoephedrine Hydrochloride 120 mg

**12 Hour** Extended-Release Tablets, USP  
Long-Acting Nasal Decongestant

NDC 51660-492-21

NON-DROWSY

**ohm**

†Compare To the active ingredient of Sudafed® 12 Hour.

# 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

Expiration Date:

NON VARNISH

Batch No.

ohm  
Pseudoephedrine Hydrochloride 120 mg  
12 Hour Extended-Release Tablets, USP  
Long-Acting Nasal Decongestant  
NON-DROWSY

†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:  
Ohm Laboratories Inc.  
New Brunswick, NJ 08901

R0419



## PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, extended release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51660-492
<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:7CUC9DD19F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CASTOR OIL (UNII: D5340Y2I9G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (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:51660-492-21	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** - Ohm Laboratories Inc. (184769029)**Registrant** - Ohm Laboratories Inc. (184769029)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(51660-492)

