PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated

Ohm Laboratories Inc.

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
children under 12 years	do not use this product in children under 12 years of age

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, magnesium stearate, microcrystalline cellulose, titanium dioxide

Questions?

call **1-800-406-7984**

Distributed by: Ohm Laboratories Inc. New Brunswick, NJ 08901

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

[†]Compare To the active ingredient of Sudafed[®] Sinus Congestion 12 Hour

NDC 51660-204-69

ohm®

NON-DROWSY

Pseudoephedrine Hydrochloride 120 mg

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

- SINUS PRESSURE + CONGESTION
- MAXIMUM STRENGTH

10 Coated Capsule-Shaped Tablets 120 mg Each

PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51660-204

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) PSEUDOEPHEDRINE HYDROCHLORIDE 120 mg

Inactive Ingredients		
Ingredient Name	Strength	
CASTOR OIL (UNII: D5340Y2I9G)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

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

Packaging			
Item Code Package Description		Marketing Start Date	Marketing End Date
NDC:51660- 204-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/28/2006	
NDC:51660- 204-21 20 in 1 BLISTER PACK; Type 0: Not a Combination Product		04/28/2006	

Marketing Information			
Marketing Application Number or Monograph Category 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(51660-204)	

Revised: 1/2024 Ohm Laboratories Inc.