

PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, extended release

DISCOUNT DRUG MART

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
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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
DRUG MART-FOOD FAIR
MEDINA, OHIO 44256**

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

DISCOUNT

drug

mart

FOOD FAIR

MAY CONTAIN

ANTI-THEFT

DEVICE

Non-Drowsy

12 Hour

Nasal Decongestant

Pseudoephedrine Hydrochloride 120 mg

Extended-Release Tablets, USP

12 Hour Long-Acting Nasal Decongestant

*Compare to the active ingredient of SUDAFED® 12 Hour

□ SINUS PRESSURE + CONGESTION

□ MAXIMUM STRENGTH

10

Coated Capsule-Shaped

Tablets (120 mg each)

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(in each tablet)
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 ■ 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

Drug Facts (continued)

Directions
 adults and children ■ take 1 tablet every 12 hours in 12 years and over ■ 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, hydroxypropylcellulose, magnesium stearate, titanium dioxide

Questions? call 1-800-408-7984



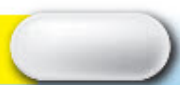
12 Hour Nasal Decongestant
 Pseudoephedrine Hydrochloride 120 mg
 Extended-Release Tablets, USP



Non-Drowsy

12 Hour Nasal Decongestant
 Pseudoephedrine Hydrochloride 120 mg
 Extended-Release Tablets, USP

12 Hour Long-Acting Nasal Decongestant



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

- ✓ SINUS PRESSURE + CONGESTION
- ✓ MAXIMUM STRENGTH

10
 Coated Capsule-Shaped
 Tablets (120 mg each)

Expiration Date:
 *All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Sudafed® 12 Hour.

NON VARNISH

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

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 MEDINA, OHIO 44256 54

SATISFACTION GUARANTEED
 IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED. IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256



pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-204
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
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

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
1	NDC:53943-204-10	1 in 1 CARTON	03/02/2018	
1		10 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
ANDA	ANDA077442	03/02/2018	

Labeler - DISCOUNT DRUG MART (047741335)

Registrant - OHM LABORATORIES INC. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(53943-204)

Revised: 3/2019

DISCOUNT DRUG MART