PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated, extended release Walgreen Company

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

Directions

adults and children	 take 1 tablet every 12 hours do not take more than 2 tablets
12 years and over	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, microcrystalline cellulose, magnesium stearate, titanium dioxide

Questions?

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

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

Walgreens

Compare to the active ingredient in Sudafed $^{ ext{ iny B}}$ 12 Hour ††

NDC 0363-0204-20

NON-DROWSY

NASAL DECONGESTANT D

PSEUDOEPHEDRINE HCl 120 mg EXTENDED-RELEASE TABLETS, USP LONG-ACTING NASAL DECONGESTANT

12 HOUR MAXIMUM STRENGTH • SINUS PRESSURE & CONGESTION

20 COATED CAPLETS * (*Capsule - shaped tablets) 120 mg EACH



PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0204	
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			

ı	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	NDC:0363- 0204-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/28/2006		
	NDC:0363- 0204-20	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/16/2019		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077442	04/28/2006	

Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations

Ohm Laboratories Inc. 051565745 MANUFACTURE(0363-0204)

Revised: 5/2022 Walgreen Company