

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

CVS Pharmacy

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: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 120 mg Caplet Blister Pack Carton

CVSHealth™

Compare to the active ingredient
in Sudafed® 12 Hour†

Non-Drowsy

Nasal Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE
EXTENDED-RELEASE TABLETS, USP 120 mg
Long-acting nasal decongestant

MAXIMUM STRENGTH

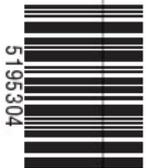
Relieves:

- SINUS PRESSURE + CONGESTION

12
HOUR

10 COATED CAPLETS*
(*Capsule-Shaped Tablets, 120 mg EACH)

Actual Size



5195304

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(in each tablet)
Pseudoephedrine HCl, USP 120 mg.....Nasal decongestant

Uses
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Temporarily relieves sinus congestion and pressure

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Ask a doctor before use if you have
heart disease high blood pressure
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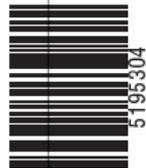
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5195304



Non-Drowsy
Nasal Decongestant

Non-Drowsy
Nasal Decongestant

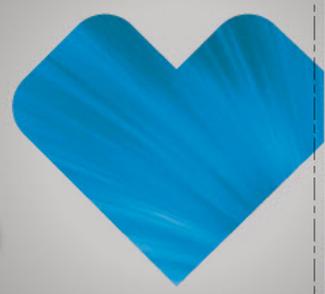


Compare to the active ingredient in Sudafed® 12 Hour†

Non-Drowsy
Nasal Decongestant
PSEUDOEPHEDRINE HYDROCHLORIDE
EXTENDED-RELEASE TABLETS, USP 120 mg
Long-acting nasal decongestant

MAXIMUM STRENGTH

Relieves:
• SINUS PRESSURE + CONGESTION



10 COATED CAPLETS*
(*Capsule-Shaped Tablets, 120 mg EACH)



Actual Size

Expiration Date:

Batch No.:

NON VARNISH

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

R0319

#465805

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One CVS Drive, Woonsocket, RI 02895
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V-14017

Keep the carton.
It contains Important Information.
See side panel for expiration date.



PLEASE RECYCLE



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PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-204
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:59779-204-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/28/2006	
2	NDC:59779-204-21	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 - CVS Pharmacy (062312574)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(59779-204)

Revised: 4/2019

CVS Pharmacy