

**SINUS AND NASAL DECONGESTANT- pseudoephedrine hydrochloride tablet,
film coated, extended release
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

CVS Pharmacy, Inc. SINUS & NASAL DECONGESTANT Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 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	<ul style="list-style-type: none">• 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

- **each tablet contains:** calcium 45 mg
- store at 20-25°C (68-77°F) in a dry place
- protect from light
- **do not use if blister unit is broken or torn**
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP *Drug Release Test 3*

Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

CVS™

12 HR

actual size

Non-Drowsy

SINUS & NASAL DECONGESTANT

Pseudoephedrine Hydrochloride Extended-Release Tablets, 120 mg

Nasal Decongestant

Compare To Sudafed® Sinus Congestion 12 Hour active ingredient

10 COATED CAPLETS†

†Capsule-Shaped Tablets

Maximum Strength 12-Hour Relief of: Sinus pressure & congestion



Non-Drowsy
SINUS & NASAL DECONGESTANT

10 COATED CAPLETS[†]
[†]Capsule-Shaped Tablets

NDC 51316-616-52



actual size



Non-Drowsy
**SINUS & NASAL
DECONGESTANT**

Pseudoephedrine Hydrochloride Extended-Release Tablets, **120 mg**
Nasal Decongestant

Compare to Sudafed® Sinus Congestion 12 Hour active ingredient*

10
COATED CAPLETS[†]
[†]Capsule-Shaped Tablets

Maximum Strength 12-Hour Relief of:
Sinus pressure & congestion

05452 17 C12

Drug Facts

Active ingredient (in each tablet) **Purpose**
Pseudoephedrine HCl 120 mg... Nasal decongestant

Uses

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- temporarily relieves sinus congestion and pressure

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Drug Facts (continued)

Directions

- | | |
|---------------------------------------|---|
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*This product is not manufactured by McNeil Consumer Healthcare Division of McNeil-PPC, Inc., distributor of Sudafed® Sinus Congestion 12 Hour.



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#465805



SINUS AND NASAL DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-616
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	L054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-616-52	10 in 1 CARTON	01/20/2026	
1		1 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	ANDA075153	01/20/2026	

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Revised: 1/2026

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED