

12 HOUR NASAL DECONGESTANT- pseudoephedrine hydrochloride tablet, film coated, extended release
CVS Pharmacy

CVS Pharmacy, Inc. 12 Hour 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

Compare to the active ingredient in Sudafed® Sinus Congestion 12 Hour Caplets

Non-Drowsy

Sinus

12 Hour Nasal Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 120 mg NASAL DECONGESTANT

MAXIMUM STRENGTH

Sinus Pressure

Congestion

12 HOUR

10 COATED CAPLETS*

*Capsule-shaped tablets

Actual Size

This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc., distributor of Sudafed® Sinus Congestion 12 Hour Caplets.
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Drug Facts (continued)

Active ingredient (in each tablet) Pseudoephedrine HCl 120 mg extended-release. Nasal decongestant.

Purpose Temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies.

Uses Temporarily relieves sinus congestion and pressure.

Warnings Do not use if you are now taking a prescription medicine or x-dase inhibitor (MAOI) (certain drugs for depression, psychiatric, or remotion at 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 or 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)

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- This product meets the requirements of USP Drug Release Test 3

Inactive ingredients camphor wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyorbate 80, titanium dioxide

Questions or comments? 1-800-719-260

Non-Drowsy • Sinus
12 Hour Nasal Decongestant
 PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 120 mg
 NASAL DECONGESTANT

CVS Health Compare to the active ingredient in Sudafed® Sinus Congestion 12 Hour Caplets†
 NDC 59779-703-52

Non-Drowsy • Sinus
12 Hour Nasal Decongestant
 PSEUDOEPHEDRINE HYDROCHLORIDE
 EXTENDED-RELEASE TABLETS, 120 mg
 NASAL DECONGESTANT

MAXIMUM STRENGTH

- Sinus pressure
- Congestion

12 HOUR

10 COATED CAPLETS*
 *Capsule-shaped tablets

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12 HOUR NASAL DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-703
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (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:59779-703-60	20 in 1 CARTON	09/11/2000	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59779-703-52	10 in 1 CARTON	12/01/1999	
2		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	12/01/1999	

Labeler - CVS Pharmacy (062312574)

Revised: 5/2019

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