

SUDAFED SINUS CONGESTION 12 HOUR- pseudoephedrine hydrochloride tablet, film coated, extended release
A-S Medication Solutions

Sudafed Sinus Congestion 12 Hour

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 torn or broken**
- 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?

call **1-888-217-2117** (toll-free) or **215-273-8755** (collect)

HOW SUPPLIED

Product: 50090-4629

NDC: 50090-4629-0 10 TABLET, FILM COATED, EXTENDED RELEASE in a BLISTER PACK / 1 in a CARTON

Pseudoephedrine Hydrochloride

NDC 50090-4629-0
A-S Medication Solutions, LLC
Product No. 6088-0
LOT

SUDAFED
SINUS CONGESTION 12 HOUR
PSEUDOEPHEDRINE HCL
EXTENDED-RELEASE TABLETS
120 MG

MAXIMUM STRENGTH
NON-DROWSY
IN EACH TABLET
PSEUDOEPHEDRINE HCL 120 MG
PURPOSE: NASAL DECONGESTANT
STORE AT 68 TO 77 DEGREES F
IN A DRY PLACE
PROTECT FROM LIGHT
10 COATED CAPLETS

DOSAGE: SEE PACKAGE INSERT
GTIN: 00350090462906
LOT:
EXP:
S/N:

DISTRIBUTED BY:
A-S Medication Solutions
Libertyville, IL 60048

SOURCE NDC: 50580-242-01



SUDAFED SINUS CONGESTION 12 HOUR

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4629(NDC:50580-242)
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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	19mm
Flavor		Imprint Code	SU12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4629-0	1 in 1 CARTON	10/21/2019	
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	ANDA075153	06/17/2019	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4629)

Revised: 10/2023

A-S Medication Solutions