

SUDAFED SINUS CONGESTION 12 HOUR- pseudoephedrine hydrochloride tablet, film coated, extended release
Johnson & Johnson Consumer Inc.

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)

PRINCIPAL DISPLAY PANEL

PREVIOUSLY SUDAFED[®] 12 HOUR
NDC 50580-242-01

SUDAFED[®]

SINUS
CONGESTION 12 HOUR

Pseudoephedrine HCl Extended-Release Tablets USP, 120 mg
Nasal Decongestant

actual size

MAXIMUM STRENGTH
SINUS PRESSURE
+ CONGESTION

10 COATED CAPLETS*

*CAPSULE-SHAPED TABLETS

NON-DROWSY



3 0081-0670-13 5

SUDAFED®

Active ingredient made in Germany
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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SUDAFED®

CODE AREA

4B552 MN C2

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Stop use and ask a doctor if:
■ nervousness, dizziness, or sleeplessness occur
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■ heart disease ■ high blood pressure
■ thyroid disease ■ diabetes

MAOI, ask a doctor or pharmacist before taking this product. MAOI drug. If you do not know if your prescription drug contains an

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Warnings
■ temporarily relieves sinus congestion and pressure
■ temporarily relieves nasal congestion due to the common cold,
■ hay fever or other upper respiratory allergies

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

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The makers of the SUDAFED® family of products are dedicated to helping you and your family reduce head congestion and sinus pressure.

PREVIOUSLY SUDAFED® 12 HOUR

NDC 50580-242-01

SUDAFED®

SINUS CONGESTION 12 HOUR

Pseudoephedrine HCl Extended-Release Tablets USP, 120 mg
Nasal Decongestant



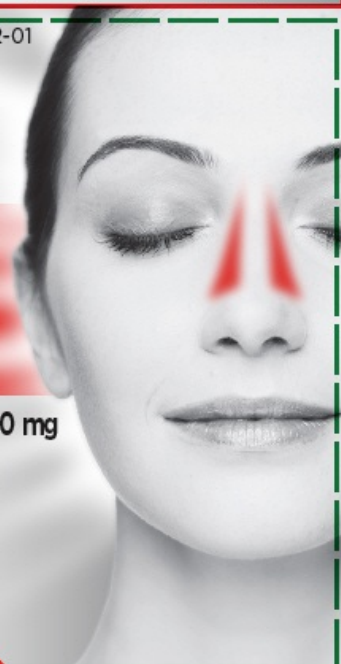
actual size

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SINUS PRESSURE
+ CONGESTION

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*CAPSULE-SHAPED TABLETS

NON-DROWSY



4B552MNC2

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SUDAFED SINUS CONGESTION 12 HOUR

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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:50580-242-01	1 in 1 CARTON	06/17/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-242-02	2 in 1 CARTON	06/17/2019	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-242-03	3 in 1 PACKAGE	06/17/2019	
3		1 in 1 CARTON		
3		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 - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.