

**SUDAFED SINUS CONGESTION 24 HOUR- pseudoephedrine hydrochloride tablet, film coated, extended release
Johnson & Johnson Consumer Inc.**

Sudafed Sinus Congestion 24 Hour

Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 240 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- relieves sinus 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
- had obstruction or narrowing of the bowel. Rarely, tablets of this kind may cause bowel obstruction (blockage), usually in people with severe narrowing of the bowel (esophagus, stomach or intestine).

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
- you experience persistent abdominal pain or vomiting

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">▪ swallow one whole tablet with water every 24 hours▪ do not exceed one tablet in 24 hours▪ do not divide, crush, chew or dissolve the tablet▪ the tablet does not completely dissolve and may be seen in the stool (this is normal)
children under 12 years	do not use this product in children under 12 years of age

Other information

- **each tablet contains:** sodium 10 mg
- store between 20 - 25 °C (68 - 77 °F)
- **do not use if blister unit is torn or broken**
- see side panel for lot number and expiration date

Inactive ingredients

cellulose triacetate, hydroxypropylcellulose, hypromellose, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, propylene glycol, shellac, sodium chloride, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

PREVIOUSLY SUDAFED[®] 24 HOUR
NDC 50580-240-01

SUDAFED[®]

SINUS

CONGESTION 24 HOUR

Pseudoephedrine HCl
Extended-Release Tablets, 240 mg
Nasal Decongestant

actual size

MAXIMUM STRENGTH
SINUS PRESSURE
+ CONGESTION

10 TABLETS
NON-DROWSY

SUDAFED®

Made in Germany
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
©J&JCI 2019

SUDAFED®



Meib USP Dissolution Test 2

call 1-888-2-17-2117 (toll-free) or 2-15-273-8755 (collect)

Questions or comments?

Inactive ingredients
cellulose, croscarmellose, hydroxypropylcellulose, hypromellose, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol, poly sorbitate 80, povidone, polyethylene glycol, shellac, sodium chondroitine, titanium dioxide

Other information

■ each tablet contains: sodium 10mg
■ store between 20-25 °C (68-77 °F)
■ do not use if blister unit is torn or broken
■ see side panel for lot number and expiration date

children under 12 years
do not use this product in children under 12 years of age

■ swallow one whole tablet with water
■ do not exceed one tablet in 24 hours
■ do not divide, crush, chew or dissolve the tablet
■ the tablet does not completely dissolve and may be seen in stool (this is normal)

Directions

Drug Facts (continued)

Stop use and ask a doctor if
■ nervousness, dizziness, or sleeplessness occur
■ symptoms do not improve within 7 days or occur with a fever
■ you experience persistent abdominal pain or vomiting
If pregnant or breastfeeding, 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)

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.
As a doctor before use if you have
■ heart disease ■ high blood pressure
■ thyroid disease ■ diabetes
■ trouble urinating due to an enlarged prostate gland
■ had obstruction or narrowing of the bowel. Rarely, tablets of this kind may cause bowel obstruction (blockage), usually in people with severe narrowing of the bowel (esophagus, stomach or intestine).

Use
Temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
■ reduces swelling of nasal passages
■ relieves sinus pressure

Drug Facts
Active ingredient (in each tablet) Pseudoephedrine HCl 240 mg
Purpose Nasal decongestant

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

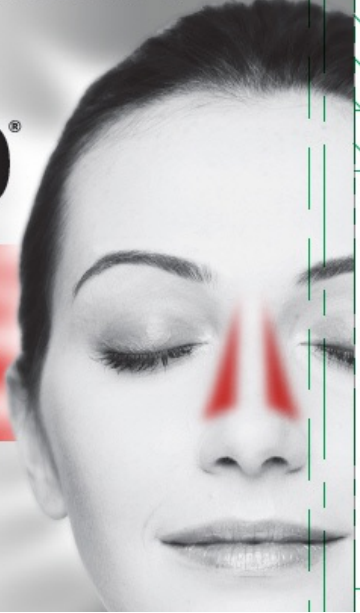
PREVIOUSLY SUDAFED® 24 HOUR

NDC 50580-240-01

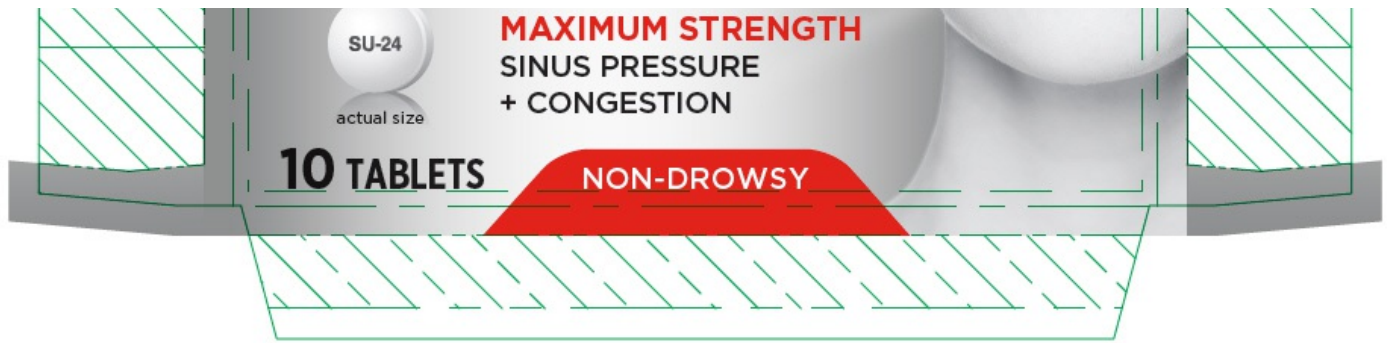
SUDAFED®

SINUS CONGESTION 24 HOUR

Pseudoephedrine HCl
Extended-Release Tablets, 240 mg
Nasal Decongestant



300 42 433



SUDAFED SINUS CONGESTION 24 HOUR

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-240
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	240 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	SU;24
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-240-01	1 in 1 CARTON	06/17/2019	09/30/2025
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
NDA	NDA020021	06/17/2019	09/30/2025

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.