

**SUDAFED SINUS CONGESTION 12 HOUR- pseudoephedrine hydrochloride tablet, film coated, extended release**  
Kenvue Brands LLC

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**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"><li>▪ take 1 tablet every 12 hours</li><li>▪ do not take more than 2 tablets in 24 hours</li></ul>
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<sup>®</sup> 12 HOUR  
NDC 50580-242-01

SUDAFED<sup>®</sup>

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  
©1&JCI2019 30042437



# SUDAFED®

# CODE AREA

4B552 MN C2

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If pregnant or breast-feeding, ask a health professional before use. Symptoms do not improve within 7 days or occur with a fever

Stop use and ask a doctor if:  
■ nervousness, dizziness, or sleeplessness occur  
■ trouble urinating due to an enlarged prostate gland

When using this product do not exceed recommended dosage

Ask a doctor before use if you have:  
■ 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

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

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

Questions or comments?  
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■ in 24 hours

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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.

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NDC 50580-242-01

# SUDAFED®

## SINUS CONGESTION 12 HOUR

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Nasal Decongestant



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SINUS PRESSURE  
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4B552MNC2

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# SUDAFED SINUS CONGESTION 12 HOUR

pseudoephedrine hydrochloride tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-242
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	SU12
<b>Contains</b>			

## 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			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075153	06/17/2019	

**Labeler** - Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC