

**SUDAFED SINUS CONGESTION- pseudoephedrine hydrochloride tablet, film coated**  
**Kenvue Brands LLC**

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**SUDAFED Sinus Congestion**

***Drug Facts***

**Active ingredient (in each tablet)**

Pseudoephedrine HCl 30 mg

**Purpose**

Nasal decongestant

**Uses**

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

**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 dose**

**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 2 tablets every 4 to 6 hours</li><li>▪ do not take more than 8 tablets in 24 hours</li></ul>
children ages 6 to 11 years	<ul style="list-style-type: none"><li>▪ take 1 tablet every 4 to 6 hours</li><li>▪ do not take more than 4 tablets in 24 hours</li></ul>
children under 6 years	do not use this product in children under 6 years of age

## Other information

- 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

carnauba wax, colloidal silicon dioxide, D&C yellow no. 10 aluminum lake, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide

## Questions or comments?

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

## PRINCIPAL DISPLAY PANEL

PREVIOUSLY SUDAFED<sup>®</sup> CONGESTION  
NDC 50580-363-02

SUDAFED<sup>®</sup>

SINUS  
CONGESTION

Pseudoephedrine HCl 30 mg,  
Nasal Decongestant

actual size

MAXIMUM STRENGTH

- SINUS PRESSURE
- SINUS CONGESTION

24 TABLETS

NON-DROWSY

# SUDAFED<sup>®</sup>

Active ingredient made in Germany

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
©J&JCI 2020

# SUDAFED<sup>®</sup>



call 1-888-217-2117 (toll-free) or 215-273-0755 (collect)

### Questions or comments?

**Inactive ingredients** carnauba wax, colloidal silicon dioxide, D&C yellow no. 10 aluminum lake, 40 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, iron oxide, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide

■ see side panel for lot number and expiration date

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■ store between 20° - 25°C (68° - 77°F)

### Other information

adults and children	■ take 2 tablets every 4 to 6 hours
12 years and over	■ do not take more than 6 tablets in 24 hours
children ages 6 to 11 years	■ take 1 tablet every 4 to 6 hours
do not use this product in children under 6 years of age	■ do not take more than 4 tablets in 24 hours

### Drug Facts (continued)

### Directions

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)

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

When using this product do not exceed recommended dose

■ trouble urinating due to an enlarged prostate gland

■ thyroid disease ■ diabetes

■ heart disease ■ high blood pressure

### Ask a doctor before use if you have

doctor or pharmacist before taking this product.

drug. If you do not know if your prescription drug contains an MAOI, ask a

conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI

inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional

Do not use if you are now taking a prescription monoamine oxidase

### Warnings

or other upper respiratory allergies

■ temporarily relieves sinus congestion and pressure

■ temporarily relieves nasal congestion due to the common cold, hay fever

### Uses

Pseudoephedrine HCl 30 mg

Nasal decongestant

### Purpose

Active ingredient (in each tablet)

### Drug Facts

Keep this box for important information.

Important: Read all product information before using.

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

PREVIOUSLY SUDAFED<sup>®</sup> CONGESTION

NDC 50580-363-02

# SUDAFED<sup>®</sup>

## SINUS CONGESTION

Pseudoephedrine HCl 30 mg,  
Nasal Decongestant



actual size

### MAXIMUM STRENGTH

- SINUS PRESSURE
- SINUS CONGESTION

24 TABLETS

NON-DROWSY



## SUDAFED SINUS CONGESTION

pseudoephedrine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-363
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	SU
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-363-01	4 in 1 CARTON	07/31/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-363-02	2 in 1 CARTON	07/31/2021	
3		12 in 1 BLISTER PACK; Type 0: Not a Combination		

4		Product		
3	NDC:50580-363-03	3 in 1 PACKAGE	02/07/2022	
3		2 in 1 CARTON		
3		12 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
OTC Monograph Drug	M012	07/31/2021	

Labeler - Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC