

**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® CONGESTION  
NDC 50580-363-02

SUDAFED®

SINUS  
CONGESTION

Pseudoephedrine HCl 30 mg,  
Nasal Decongestant

actual size

MAXIMUM STRENGTH

- SINUS PRESSURE
- SINUS CONGESTION

24 TABLETS

NON-DROWSY

**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

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Drug Facts (continued)	
Directions	
adults and children take 2 tablets every 4 to 6 hours	do not take more than 3 tablets in 24 hours
12 years and over take 2 tablets every 4 to 6 hours	do not take more than 3 tablets in 24 hours
children take 1 tablet every 4 to 6 hours	do not take more than 1 tablet in 24 hours
6 to 11 years take 1 tablet every 4 to 6 hours	do not take more than 1 tablet in 24 hours
6 years or older children under	do not use this product in children under 6 years
see side panel for full number and expiration date	
store between 20-25°C (68-77°F)	
do not use if blister unit is torn or broken	
see side panel for full number and expiration date	
■ active ingredients same as above, colloidal silicon dioxide, D&C yellow 10, aluminum lake, hydroxyethyl cellulose, iron red no. 40, aluminum lake, FD&C yellow 5, FD&C red no. 40, aluminum lake, FD&C blue no. 1, magnesium stearate, talc, titanium dioxide, pregelatinized starch, sodium starch glycolate, polyvinyl alcohol.	
no. 6 aluminum lake, hydroxyethyl cellulose, iron green 3, FD&C yellow 5, FD&C red no. 40, aluminum lake, FD&C red no. 40, aluminum lake, FD&C blue no. 1, magnesium stearate, talc, titanium dioxide, colloidal silicon dioxide, D&C yellow 10, aluminum lake, hydroxyethyl cellulose, iron red no. 40, aluminum lake, FD&C yellow 5, FD&C red no. 40, aluminum lake, FD&C blue no. 1, magnesium stearate, talc, titanium dioxide, pregelatinized starch, sodium starch glycolate, polyvinyl alcohol.	
Questions or comments? call 1-888-217-2117 (toll-free) or 215-273-8755 (collect)	

Drug Facts	
Active ingredient (in each tablet)	
Pseudoephedrine HCl 30 mg	Nasal decongestant
■ Larmopropyl relaxes sinus congestion and pressure or other upper respiratory allergies	
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) or certain drugs for depression, psychotrophic or anticonvulsant drugs, or if you do not know if you are taking this drug with 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	
Stop using this product do not exceed recommended dose ■ nervousness, dizziness, or pressuriness occur ■ symptoms of cold occur after 7 days of 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)	

SUDAFED

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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 SUAEEF® CONGESTION

NDC 50580-363-02

# SUDAFED®

# SINUS CONGESTION

### **Pseudoephedrine HCl 30 mg, Nasal Decongestant**



## MAXIMUM STRENGTH

- SINUS PRESSURE
  - SINUS CONGESTION

**24 TABLETS**

**NON-DROWSY**

## **SUDAFED SINUS CONGESTION**

pseudoephedrine hydrochloride tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-363
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<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

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	SU
<b>Contains</b>			

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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		

	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