

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

---

**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® 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



**CODE AREA**

4B552 MN C2

4B552MN C2

# 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 -** Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC