

**CHILDRENS SUDAFED NASAL DECONGESTANT- pseudoephedrine hydrochloride solution**  
**Johnson & Johnson Consumer Inc.**

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**Children's Sudafed**

**Nasal Decongestant**

***Drug Facts***

**Active ingredient (in each 5 mL)**

Pseudoephedrine HCl 15 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
- promotes nasal and/or sinus drainage

**Warnings**

**Do not use** in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if the child has**

- heart disease
- high blood pressure
- thyroid disease
- diabetes

**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

**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**

- find right dose on chart below
- mL = milliliter
- repeat dose every 4 to 6 hours
- do not use more than 4 times in 24 hours

Age (yr)	Dose (mL)
under 4 years	do not use
4 to 5 years	5 mL
6 to 11 years	10 mL

**Attention:** use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

**Other information**

- **each 5 mL contains:** sodium 5 mg
- store between 20-25°C (68-77°F)
- **do not use if bottle wrap, or foil inner seal imprinted "SAFETY SEAL®" is broken or missing**

**Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, menthol, poloxamer 407, polyethylene glycol, povidone K-90, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution

**Questions or comments?**

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

**PRINCIPAL DISPLAY PANEL**

NDC 50580-536-04

**children's**  
**SUDAFED®**

**non-drowsy**

**NASAL**  
**DECONGESTANT**

**Pseudoephedrine HCl Oral Solution**  
**Nasal Decongestant**

RELIEF OF

- **Stuffy Nose**
- **Sinus Pressure**

**Grape**  
**FLAVOR LIQUID**  
**ALCOHOL &**  
**SUGAR FREE**

**4 fl oz (118 mL) 15 mg per 5 mL**



CHILDRENS SUDAFED NASAL DECONGESTANT

pseudoephedrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-536
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	15 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZ B9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics			
Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-536-04	1 in 1 CARTON	10/01/2008	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/01/2008	

**Labeler** - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.