

CHILDRENS SUDAFED NASAL DECONGESTANT- pseudoephedrine hydrochloride solution
Kenvue Brands LLC

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



Drug Facts (continued)

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Active ingredient made in Germany
 Distributed by:
JOHNSON & JOHNSON
 CONSUMER INC.
 McNeil Consumer Healthcare Division
 Fort Washington, PA 19084 USA
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3003888

Actual Size

Other Products Formulated To Relieve Your Child's Symptoms

Tips for Relieving Stuffy Nose Symptoms

- Make sure they drink lots of fluids, especially warm drinks
- Show them how to breathe in moist air from a hot shower, humidifier or vaporizer
- When treating your child's symptoms, be sure to use the dosing cup to properly dose medication



How can we help?
 1-888-217-2117
 sudafed.com

children's SUDAFED

non-drowsy

NASAL DECONGESTANT

Pseudoephedrine HCl Oral Solution
 Nasal Decongestant

RELIEF OF
 Stuffy Nose
 Sinus Pressure



LOT/EXP

children's SUDAFED
 non-drowsy
NASAL DECONGESTANT

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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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

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 - Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC