

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

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Childrens Sudafed PE**

**NASAL DECONGESTANT**

***Drug Facts***

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

Phenylephrine HCl 2.5 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** 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
- a sodium-restricted diet

**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 hours
- do not use more than 6 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 14 mg
- store between 20-25°C (68-77°F). Protect from light. Store in outer carton until contents are used.
- **do not use if carton tape or bottle wrap imprinted with "Sealed For Your Safety" is broken or missing**

### Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, edetate disodium, FD&C red no. 40, flavors, glycerin, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

### Questions or comments?

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

### PRINCIPAL DISPLAY PANEL

NDC 50580-784-04

children's  
SUDAFED®  
PE

non-drowsy

NASAL  
DECONGESTANT

Phenylephrine HCl Oral Solution  
Nasal Decongestant

RELIEF OF

- Stuffy Nose
- Sinus Pressure

Berry

FLAVOR LIQUID

ALCOHOL &

SUGAR FREE

4 fl oz (118 mL) 2.5 mg per 5 mL

children's  
**SUDAFED**<sup>®</sup>  
PE

How can we help?

☎ 1-888-217-2117

sudafed.com

NDC 50580-784-04

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ALCOHOL &  
SUGAR FREE

4 fl oz (118 mL) 2.5 mg per 5 mL

Active ingredient made in India

Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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30046181



■ symptoms do not improve within 7 days or occur with a fever

**Drug Facts** (continued)

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Actual Size

children's  
**SUDAFED**  
PE

children's  
**SUDAFED**  
PE



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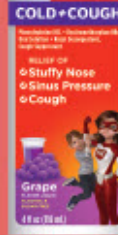
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3 0045-0537-04 1



available behind  
the counter

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

## CHILDRENS SUDAFED PE NASAL DECONGESTANT

phenylephrine hydrochloride solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-784
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	RASPBERRY (BERRY)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-784-04	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 final	part341	10/01/2008	

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