

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

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[®]
PE

How can we help?

☎ 1-888-217-2117

sudafed.com

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



children's
SUDAFED[®]
PE

non-drowsy

**NASAL
DECONGESTANT**

Drug Facts

Active ingredient (in each 5 mL)	Purpose
Phenylephrine HCl 2.5 mg.....	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

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
©J&JCI 2019

30046181



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

Drug Facts (continued)

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.

Actual Size

children's
SUDAFED
PE

children's
SUDAFED
PE

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)



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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	RASPBERRY (BERRY)	Imprint Code	
Contains			

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 Drug	M012	10/01/2008	

Labeler - Johnson & Johnson Consumer Inc. (878046358)