CHILDRENS SUDAFED PE NASAL DECONGESTANT- phenylephrine hydrochloride solution
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

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.

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

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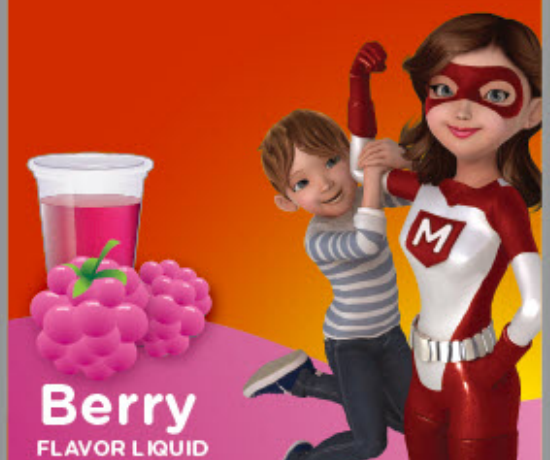

Berry
FLAVOR LIQUID

children's SUDAFED® PE

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ALCOHOL & SUGAR FREE

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

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

Active ingredient made in India

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

30046181

Drug Facts (continued)

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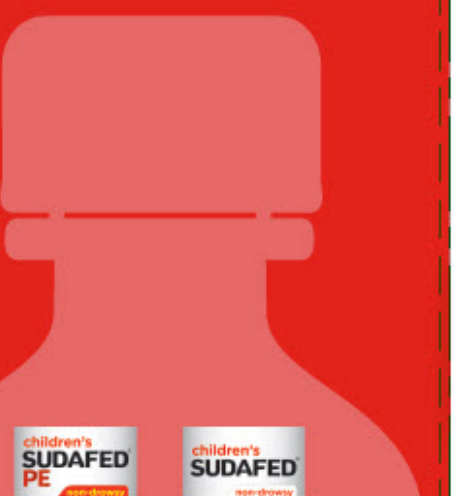
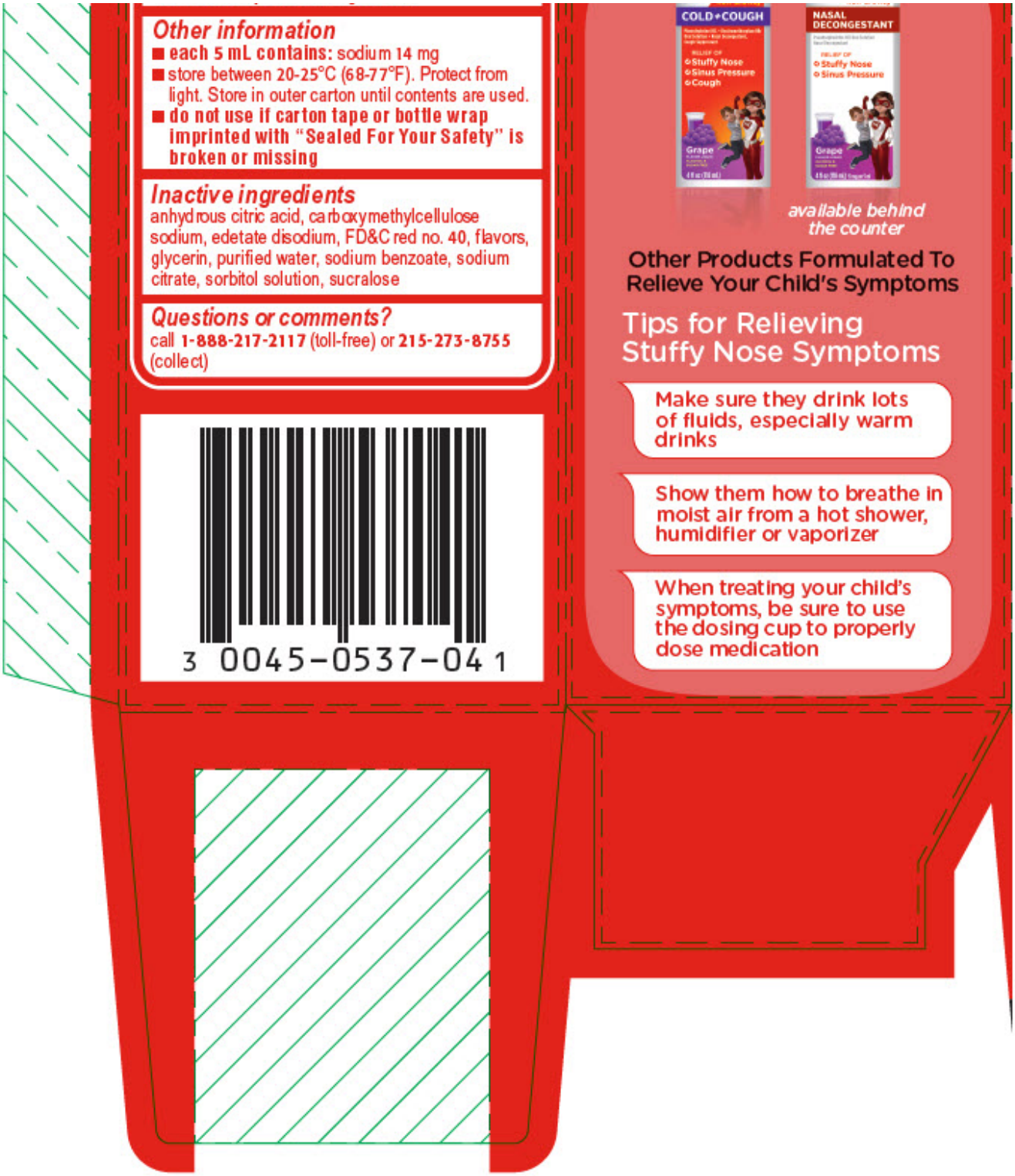
Actual Size





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
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: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate, unspecified form (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
sucralose (UNII: 96K6UQ3ZD4)	

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 FINAL	part341	10/01/2008	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 3/2021 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division