CHILDRENS SUDAFED PE COLD PLUS COUGH- dextromethorphan hydrobromide and phenylephrine hydrochloride solution
Johnson & Johnson Consumer Inc.

Children's SUDAFED PE Cold plus Cough

Drug Facts

Active ingredients (in each 5 mL)	***Purposes***
Dextromethorphan HBr 5 mg	Cough suppressant
Phenylephrine HCl 2.5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to the common cold, hay fever, or other upper respiratory allergies:
  - cough
  - nasal congestion
  - 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
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)
- 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
- cough gets worse or lasts for more than 7 days
- cough tends to come back or occurs with fever, rash or headache that lasts

These could be signs of a serious condition.

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 = milliliters
- repeat dose every 4 hours
- do not give 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 blue no. 1, 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 50580-785-04

children's
SUDAFED ®
PE

non-drowsy
COLD + COUGH

Phenylephrine HCl • Dextromethorphan HBr
Nasal Decongestant • Cough Suppressant
Oral Solution

RELIEF OF

- Stuffy Nose
- Sinus Pressure
- Cough

Grape
FLAVOR LIQUID
ALCOHOL &
SUGAR FREE

4 fl oz (118 mL)

CHILDRENS SUDAFED PE COLD PLUS COUGH

dextromethorphan hydrobromide and phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-785
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
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 BLUE NO. 1 (UNII: H3R47K3TBD)	
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	purple	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-785-04	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)

Establishment

Name	Address	ID/FEI	Business Operations

Siegfried PharmaChemikalien Minden Gmbh		328153106	api manufacture(50580-785)

Revised: 1/2024 Johnson & Johnson Consumer Inc.