SUDAFED PE SINUS CONGESTION- phenylephrine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

Sudafed PE Sinus Congestion

Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

Warnings

Do not use if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

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

If pregnant or breast-feeding, ask a health professional before use.

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

adults and children 12 years and over	▪ take 1 tablet every 4 hours ▪ do not take more than 6 tablets in 24 hours
children under 12 years	ask a doctor

Other information

- store between 20-25°C (68-77°F)
- **do not use if blister unit is torn or broken**

Inactive ingredients

carnauba wax, D&C yellow no. 10 aluminum lake, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, modified starch, polyethylene glycol, polyvinyl alcohol, powdered cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

PREVIOUSLY SUDAFED PE ® CONGESTION
NDC 50580-437-02

SUDAFED PE®

SINUS
CONGESTION

Phenylephrine HCl, Nasal Decongestant

actual size

MAXIMUM STRENGTH

- SINUS PRESSURE
- SINUS CONGESTION

36 TABLETS

NON-DROWSY

10 mg
each

SUDAFED PE®

Active ingredient made in Germany
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA ©J&JCI 2018

Does Not Contain Pseudoephedrine

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Drug Facts (continued)

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Questions or comments?

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Important Read all product information before using. Keep this box for important information.

The makers of the SUDAFED® family of products are dedicated to helping you and your family reduce head congestion and sinus pressure.

30042471/
120482

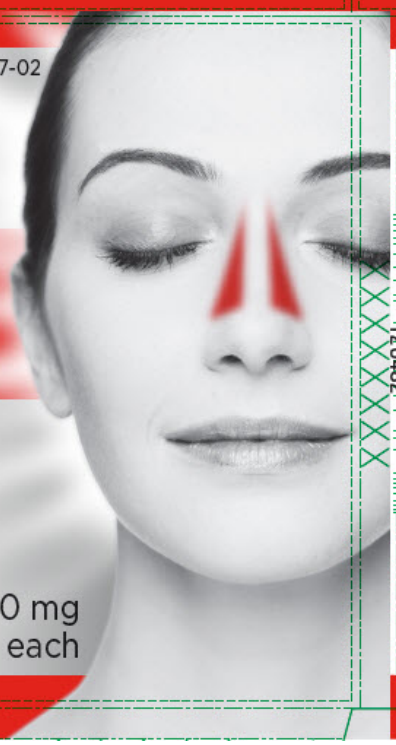
PREVIOUSLY SUDAFED PE® CONGESTION

NDC 50580-437-02

SUDAFED PE®

SINUS CONGESTION

Phenylephrine HCl, Nasal Decongestant



PE
actual size

MAXIMUM STRENGTH
- SINUS PRESSURE
- SINUS CONGESTION

10 mg each

36 TABLETS

NON-DROWSY

120482

SUDAFED PE®

SUDAFED PE SINUS CONGESTION

phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-437
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	WL;80;PE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-437-01	1 in 1 CARTON	06/17/2019	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-437-02	2 in 1 CARTON	06/17/2019	
2		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-437-03	3 in 1 PACKAGE	09/03/2019	
3		2 in 1 CARTON		
3		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/17/2019	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.