SUDAFED PE SINUS CONGESTION- phenylephrine hydrochloride tablet, film coated
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.

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	■ take 1 tablet every 4 hours ■ do not take more than 6 tablets in

children 12 years and over	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 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 (UNII: 35SW5USQ3G)	
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 potato (UNII: 5856J3G2A2)	
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	NDC:50580-437-02	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 FINAL	part341	06/17/2019	

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

Revised: 8/2019 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division