SUDAFED PE DAY PLUS NIGHT SINUS CONGESTION- diphenhydramine hydrochloride and phenylephrine hydrochloride
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® DAY + NIGHT SINUS CONGESTION

SUDAFED PE® DAYTIME

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 carton or blister unit is opened 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)

SUDAFED PE® NIGHTTIME

Drug Facts

Active ingredients (in each tablet)	***Purposes***
Diphenhydramine HCl 25 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
  - nasal congestion
- temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing
  - nasal congestion
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin
- 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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dose**
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
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PRINCIPAL DISPLAY PANEL

NDC 50580-736-01

SUDAFED$^{PE®}$

DAY+NIGHT SINUS CONGESTION

Phenylephrine HCl
Nasal Decongestant

DAYTIME

NASAL CONGESTION

12 TABLETS, 10 mg EACH

actual
size

Diphenhydramine HCl, Phenylephrine HCl
Antihistamine, Nasal Decongestant

NIGHTTIME

NASAL CONGESTION

RUNNY NOSE

***small tablet size**

8 ULTRATABS®* TABLETS
TOTAL: 20 TABLETS

The makers of the SUDAFED® family of products have been dedicated to reducing sinus pressure for over 50 years. Learn more about our full range of effective sinus products at Sudafed.com

SUDAFED.COM

NDC 50580-736-01

SUDAFED PE®

DAY+NIGHT SINUS CONGESTION

Phenylephrine HCl
Nasal Decongestant

Diphenhydramine HCl, Phenylephrine HCl
Antihistamine, Nasal Decongestant

DAYTIME

NASAL CONGESTION

12 TABLETS, 10 mg EACH

*small tablet size

NIGHTTIME

NASAL CONGESTION
RUNNY NOSE

8 ULTRATABS*† TABLETS
TOTAL: 20 TABLETS

SUDAFED PE®

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116247

DO NOT USE IF CARTON OR BLISTER UNIT IS OPENED OR BROKEN

Drug Facts (continued)

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

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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)

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Inactive ingredients

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SUDAFED PE® NIGHTTIME

NDC 50580-736-01

SUDAFED PE®

DAY+NIGHT SINUS CONGESTION

Phenylephrine HCl
Nasal Decongestant

Diphenhydramine HCl, Phenylephrine HCl
Antihistamine, Nasal Decongestant

DAYTIME

NIGHTTIME

NASAL CONGESTION

12 TABLETS, 10 mg EACH

NASAL CONGESTION
RUNNY NOSE

8 ULTRATABS*† TABLETS
TOTAL: 20 TABLETS
*small tablet size

actual size

PE

PE

Daytime Active ingredient made in Germany
Nighttime Made in Italy
Dist. by: JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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SUDAFED PE®

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- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

▲

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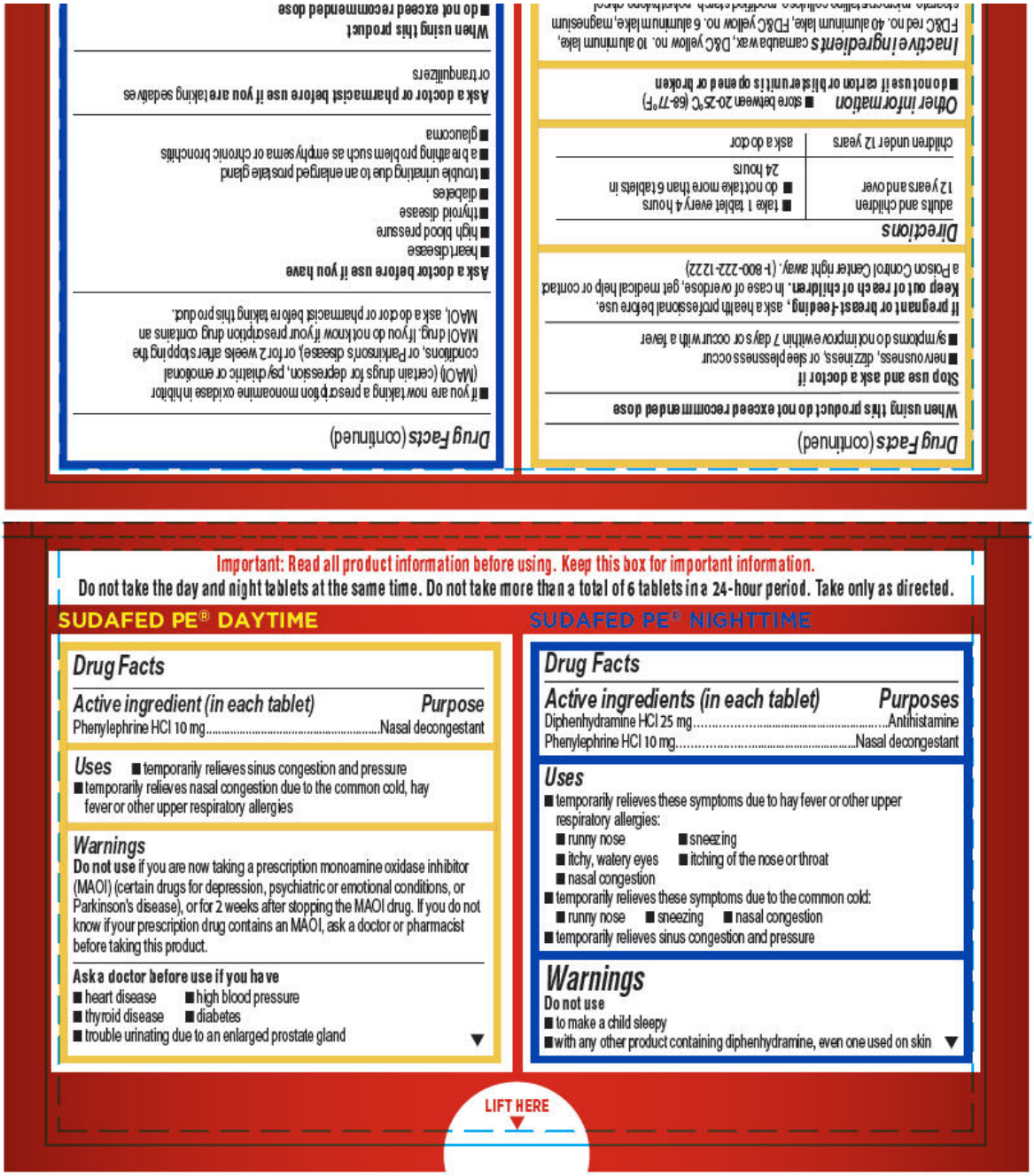
stearate, microcrystalline cellulose, modified starch, polyethylene glycol, polyvinyl alcohol, powdered cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide



SUDAFED PE DAY PLUS NIGHT SINUS CONGESTION

diphenhydramine hydrochloride and phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-736

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-736-01	1 in 1 PACKAGE	06/26/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	12
Part 2	2 BLISTER PACK	8

Part 1 of 2

SUDAFED PE CONGESTION

phenylephrine hydrochloride tablet

Product Information

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: 3WJQ0SDW1A)	
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		6 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	07/13/2015	

Part 2 of 2

SUDAFED PE SINUS CONGESTION PLUS ALLERGY

diphenhydramine hydrochloride and phenylephrine hydrochloride tablet, film coated

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	25 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg

Inactive Ingredients

Ingredient Name	Strength
carnauba wax (UNII: R12CBM0EIZ)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LMI26O6933)	
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	BLUE	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	PE;WL95
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1		4 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	06/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/26/2017	

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

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