

SUDAFED PE SINUS CONGESTION- diphenhydramine hydrochloride and phenylephrine hydrochloride
Kenvue Brands LLC

SUDAFED PE 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	<ul style="list-style-type: none">take 1 tablet every 4 hoursdo 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)

SUDAFED PE[®] NIGHTTIME

Drug Facts

Active ingredients (in each tablet)	Purpose
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
- 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	<ul style="list-style-type: none"> take 1 tablet every 4 hours do not take more than 6 tablets in 24 hours
children under 12	ask a doctor

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, FD&C blue no. 1 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[®] DAY + NIGHT SINUS CONGESTION
NDC 50580-239-01

SUDAFED PE[®]

SINUS CONGESTION

Phenylephrine HCl
Nasal Decongestant

DAYTIME

- NASAL
CONGESTION

actual size

12 TABLETS 10 mg each

Diphenhydramine HCl, Phenylephrine HCl
Antihistamine, Nasal Decongestant

NIGHTTIME

- NASAL CONGESTION
- RUNNY NOSE

actual size

8 TABLETS | TOTAL: 20 TABLETS

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

PREVIOUSLY SUDAFED PE® DAY + NIGHT SINUS CONGESTION NDC 50580-239-01

SUDAFED^{PE}

SINUS CONGESTION

Phenylephrine HCl
Nasal Decongestant

Diphenhydramine HCl, Phenylephrine HCl
Antihistamine, Nasal Decongestant



DAYTIME

• NASAL CONGESTION

actual size

12 TABLETS 10 mg each

NIGHTTIME

• NASAL CONGESTION
• RUNNY NOSE

actual size

8 TABLETS | TOTAL: 20 TABLETS

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SUDAFED^{PE}

Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA ©J&JCI 2018

Daytime: Active ingredient made in Germany | Nighttime: Made in Italy

Does not contain Pseudoephedrine

SUDAFED^{PE} NIGHTTIME

Drug Facts (continued)

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	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 - camphor, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, modified starch, polyethylene glycol, polyvinyl alcohol, powdered cellulose, pregelatinized starch, sodium starch glycolate, xanthan gum, titanium dioxide

Questions or comments?
call 1-888-217-2117 (toll-free) or 215-273-8755 (collect)

DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN

SUDAFED^{PE} SINUS CONGESTION

NDC 50580-239-01

DAYTIME

Phenylephrine HCl
Nasal Decongestant

12 TABLETS 10 mg each

NIGHTTIME

Diphenhydramine HCl, Phenylephrine HCl
Antihistamine, Nasal Decongestant

8 TABLETS

TOTAL: 20 TABLETS

SUDAFED^{PE}

Stop use and ask a doctor if:

- symptoms do not improve within 7 days or occur with a fever
- nervousness, dizziness, or sleepiness occur

Excitability may occur, especially in children

Be careful when driving a motor vehicle or operating machinery

Alcohol, sedatives, and tranquilizers may increase drowsiness

Questions or comments?
call 1-888-217-2117 (toll-free) or 215-273-8755 (collect)

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, xanthan gum, titanium dioxide

<p>Drug Facts (continued)</p> <p>When using this product do not exceed recommended dose</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ nervousness, dizziness, or sleepiness occur ■ symptoms do not improve within 7 days or occur with a fever <p>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)</p> <p>Directions</p> <table border="1"> <tr> <td>adults and children</td> <td>■ take 1 tablet every 4 hours</td> </tr> <tr> <td>12 years and over</td> <td>■ do not take more than 6 tablets in 24 hours</td> </tr> <tr> <td>children under 12 years</td> <td>ask a doctor</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> ■ store between 20-25°C (68-77°F) ■ do not use if blister units torn or broken <p>Inactive ingredients carnauba wax, D & C yellow no. 10 aluminum</p>	adults and children	■ take 1 tablet every 4 hours	12 years and over	■ do not take more than 6 tablets in 24 hours	children under 12 years	ask a doctor	<p>Drug Facts (continued)</p> <p>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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ 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 <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ do not exceed recommended dose ■ marked drowsiness may occur ■ avoid alcoholic drinks
adults and children	■ take 1 tablet every 4 hours						
12 years and over	■ do not take more than 6 tablets in 24 hours						
children under 12 years	ask a doctor						

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

Do not take the day and night tablets at the same time. Do not take more than a total of 6 tablets in a 24-hour period. Take only as directed.

<p>SUDAFED PE® DAYTIME</p> <p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredient (in each tablet)</th> <th>Purpose</th> </tr> <tr> <td>Phenylephrine HCl 10 mg.....</td> <td>Nasal decongestant</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves sinus congestion and pressure ■ temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland 	Active ingredient (in each tablet)	Purpose	Phenylephrine HCl 10 mg.....	Nasal decongestant	<p>SUDAFED PE® NIGHTTIME</p> <p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredients (in each tablet)</th> <th>Purpose</th> </tr> <tr> <td>Diphenhydramine HCl 25 mg.....</td> <td>Antihistamine</td> </tr> <tr> <td>Phenylephrine HCl 10 mg.....</td> <td>Nasal decongestant</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat ■ nasal congestion ■ temporarily relieves these symptoms due to the common cold: <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ nasal congestion ■ temporarily relieves sinus congestion and pressure <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ to make a child sleepy ■ with any other product containing diphenhydramine, even one used on skin 	Active ingredients (in each tablet)	Purpose	Diphenhydramine HCl 25 mg.....	Antihistamine	Phenylephrine HCl 10 mg.....	Nasal decongestant
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SUDAFED PE SINUS CONGESTION

diphenhydramine hydrochloride and phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-239
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-239-01	1 in 1 PACKAGE	06/17/2019	

Quantity of Parts

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

Part 1 of 2

SUDAFED PE SIINUS CONGESTION

phenylephrine hydrochloride tablet, film coated

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 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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 (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		2 in 1 CARTON		

1	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
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Marketing Information

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

Part 2 of 2

SUDAFED PE SINUS CONGESTION PLUS ALLERGY

diphenhydramine hydrochloride and phenylephrine hydrochloride tablet, film coated

Product Information

Route of Administration	ORAL
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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 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
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 (UNII: H8AV0SQX4D)	
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		2 in 1 CARTON		
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 Drug	M012	06/17/2019	

Marketing Information

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

Labeler - Kenvue Brands LLC (118772437)

Revised: 11/2024

Kenvue Brands LLC