SUDAFED PE PRESSURE PLUS PAIN- acetaminophen and phenylephrine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

SUDAFED PE ® Pressure+Pain

Drug Facts

Active ingredients (in each caplet)	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
  - sinus congestion and pressure
  - headache
  - minor aches and pains
  - nasal congestion
- promotes sinus drainage
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dose

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

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

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
- **do not use more than directed (see overdose warning)**

adults and children 12 years and over	▪ take 2 caplets every 4 hours ▪ do not take more than 10 caplets 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 is opened or if blister unit is broken**

Inactive ingredients

carnauba wax, FD&C yellow no. 6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, polyethylene glycol, polysorbate 80, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

See New Warning

SINUS

NDC 50580-547-25

SUDAFED PE®
PRESSURE +PAIN
For
Adults

Acetaminophen, Phenylephrine HCl
Pain Reliever/Fever Reducer, Nasal Decongestant

SINUS PRESSURE
+ CONGESTION

SINUS HEADACHE

MAXIMUM
STRENGTH

24 CAPLETS

NON-DROWSY

‡ Actual Pill Size


Open from other side
SUDAFED PE®
Does Not Contain Pseudoephedrine
LOT:
EXP.:
3 0045-0547-24 8
Distributed by:
McNeil Consumer Healthcare
Division of McNEIL-PPC, Inc.
Fort Washington, PA 19034 USA
©MCNEIL-PPC, INC. 2016
Drug Facts
Active ingredients (in each caplet)
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■ promotes sinus drainage
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■ with other drugs containing acetaminophen
■ 3 or more alcoholic drinks every day while using this product
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■ blisters
■ rash
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■ 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.
■ if you have ever had an allergic reaction to this product or any of its ingredients
Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland
Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin
When using this product do not exceed recommended dose
Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur ■ pain or nasal congestion gets worse or lasts more than 7 days
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present ■ new symptoms occur
These could be signs of a serious condition.
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Questions or comments? call 1-888-217-2117 (toll-free) or 215-273-8755 (collect)
Important: Read all product information before using. Keep this box for important information.
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
3 0034 1824/ 10237201
See New Warning
SINUS
NDC 50580-547-25
SUDAFED PE®
PRESSURE+PAIN For Adults
Acetaminophen, Phenylephrine HCl
Pain Reliever/Fever Reducer, Nasal Decongestant
SINUS PRESSURE + CONGESTION
SINUS HEADACHE
SU PE
‡
™
MAXIMUM STRENGTH
24 CAPLETS
NON-DROWSY
‡Actual Pill Size

SUDAFED PE PRESSURE PLUS PAIN

acetaminophen and phenylephrine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-547
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange (Peach)	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	SU;PE;WL;89
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50580-547-25	2 in 1 CARTON	07/01/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-547-73	2 in 1 CARTON	12/21/2018	04/30/2021
2		12 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	07/01/2012	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 2/2024 Johnson & Johnson Consumer Inc.