

SUDAFED PE SINUS PRESSURE PLUS PAIN- acetaminophen and phenylephrine hydrochloride tablet, film coated
Sportpharm LLC

Sudafed PE Sinus Pressure Plus Pain

Drug Facts

<i>Active ingredients (in each tablet)</i>	<i>Purpose</i>
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 tablets (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	<ul style="list-style-type: none">▪ take 2 tablets every 4 hours▪ do not take more than 10 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, 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

Relabeled For:

SPORTPHARM

SUDAFED PE SINUS PRESSURE + PAIN

NDC: 85766-183-24

Qty: 24

Distributed By: Johnson & Johnson Consumer Inc.

Source NDC: 50580-435-01

Description: orange (peach);oval;film coated tablets/SUPE;WL89

Lot #: 00000000 Exp: (01) 0 0385766 18324 3 (17) (10) 00000000 (21)

Batch #: 00000000

Drug Status: OTC

Packaged By: Enoxchem Pharmaceuticals Torrance, CA 90501

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.

KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

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SUDAFED PE SINUS PRESSURE PLUS PAIN

acetaminophen and phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85766-183(NDC:50580-435)
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:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

Product Characteristics

Color	orange (PEACH)	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	SUPE;WL89
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85766-183-24	2 in 1 CARTON	03/10/2026	
1		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	03/10/2026	

Labeler - Sportpharm LLC (125298538)