SUDAFED PE HEAD CONGESTION PLUS FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

SUDAFED PE Head Congestion + Flu Severe

Drug Facts

Active ingredients (in each tablet)	***Purposes***
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to the common cold:
  - nasal congestion
  - headache
  - minor aches and pains
  - cough
  - sore throat
  - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- 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.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

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, cough 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
- cough comes back or occurs with rash or headache that lasts

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 tablets every 4 hours ▪ do not take more than 10 tablets in 24 hours
children under 12 years	ask a doctor

Other information

- contains FD&C yellow no. 5 aluminum lake (tartrazine) as a color additive
- store between 20-25°C (68-77°F)
- **do not use if carton or blister unit is opened or broken**

Inactive ingredients

carnauba wax, croscarmellose sodium, FD&C yellow no. 5 aluminum lake (tartrazine), FD&C yellow no. 6 aluminum lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

PREVIOUSLY SUDAFED PE ® PRESSURE + PAIN + COLD
NDC 50580-450-01

SUDAFED PE®

HEAD CONGESTION
+ FLU SEVERE

Acetaminophen, Dextromethorphan HBr, Guaifenesin,
Phenylephrine HCl, Pain Reliever/Fever Reducer,
Cough Suppressant, Expectorant, Nasal Decongestant

actual
size

- SINUS PRESSURE
- HEADACHE
- SORE THROAT
- COUGH

- CHEST CONGESTION

24 TABLETS

NON-DROWSY

PREVIOUSLY **SUDAFED PE® PRESSURE + PAIN + COLD** NDC 50580-450-01

SUDAFED PE®

HEAD CONGESTION + FLU *SEVERE*

Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl, Pain Reliever/Fever Reducer, Cough Suppressant, Expectorant, Nasal Decongestant

SU PE

actual size

- SINUS PRESSURE
- SORE THROAT
- CHEST CONGESTION
- HEADACHE
- COUGH

24 TABLETS

NON-DROWSY

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

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

Drug Facts

Active ingredients (in each tablet) — **Purpose**

Acetaminophen 325 mg ..... Pain reliever/fever reducer

Dextromethorphan HBr 10 mg ..... Cough suppressant

Guaifenesin 100 mg ..... Expectorant

Phenylephrine HCl 5 mg ..... Nasal decongestant

Uses

■ temporarily relieves these symptoms due to the common cold:
■ nasal congestion ■ headache ■ minor aches and pains ■ cough
■ sore throat ■ sinus congestion and pressure
■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive ■ 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.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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
■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough that occurs with too much phlegm (mucus)

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, cough 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 ■ cough comes back or occurs with rash or headache that lasts

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 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 carton or blister unit is opened or torn
■ contains FD&C yellow no. 5 aluminum lake (tartrazine) as a color additive

Inactive ingredients

carnauba wax, croscarmellose sodium, FD&C yellow no. 5 aluminum lake (tartrazine), FD&C yellow no. 6 aluminum lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol polysorbate 80, pregelatinized starch, titanium dioxide

Questions or comments?

call 1-888-327-3377 (toll-free) or 215-273-8755 (collect)

SUDAFED PE®
Does Not Contain Pseudoephedrine
Open from the other side

Made in Italy
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA ©J&JCI 2018

300450582256

30043256

SUDAFED PE HEAD CONGESTION PLUS FLU SEVERE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-450
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	SUPE;WL92
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-450-01	2 in 1 CARTON	06/17/2019	

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	06/17/2019	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.