

SUDAFED PE HEAD CONGESTION PLUS PAIN- ibuprofen and phenylephrine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

Sudafed PE Head Congestion + Pain

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purposes</i>
Ibuprofen 200 mg (NSAID) *	Pain reliever/fever reducer
Phenylephrine HCl 10 mg	Nasal decongestant

* nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves these symptoms associated with the common cold or flu:
 - headache
 - fever
 - sinus pressure
 - nasal congestion
 - minor body aches and pains
- reduces swelling of the nasal passages
- temporarily restores freer breathing through the nose

Warnings

Allergy alert

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin,

ibuprofen, naproxen, or others]

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- in children under 12 years of age because this product contains too much medication for children under this age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- 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

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other product that contains phenylephrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing

- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- symptoms continue or get worse
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

- **do not take more than directed**
- adults and children 12 years of age and over:
 - take 1 caplet every 4 hours while symptoms persist
 - do not use more than 6 caplets in any 24-hour period unless directed by a doctor
 - children under 12 years of age: do not use because this product contains too much medication for children under this age

Other information

- store between 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton.
- **do not use if blister unit is torn or broken**

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-436-01

SUDAFED PE®

HEAD CONGESTION

+ PAIN

Ibuprofen 200 mg, Phenylephrine Hydrochloride 10 mg Tablets
Pain Reliever/Fever Reducer (NSAID),
Nasal Decongestant

- NASAL CONGESTION • HEADACHE
- SINUS PRESSURE • FEVER
- NASAL SWELLING • BODY ACHES

ONE CAPLET DOSE!

actual size

20 COATED CAPLETS**

**CAPSULE-SHAPED TABLETS

NON-DROWSY

SUDAFED^{PE}

CODE AREA

4B060 MN C1

SUDAFED^{PE}

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
 McNeil Consumer Healthcare Division
 Fort Washington, PA 19034 USA
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Drug Facts (continued)

Inactive ingredients include silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyethylene glycol, stearic acid, talc, titanium dioxide.

Questions or comments? call 1-888-237-2117 (ask-4me) or 215-273-8755 (collect)

Drug Facts (continued)

Warnings Allergic alert: An allergic reaction may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: The product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older; have had stomach ulcers or bleeding problems; take a blood thinning (anticoagulant) or steroid drug; take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others); have 3 or more alcoholic drinks every day while using this product; take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use in children under 12 years of age because the product contains too much medication for children under this age. If you have ever had an allergic reaction to any other pain reliever/fever reducer, do not take or use unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get the medical help or contact a Poison Control Center right away: (1-800-222-1222).

Directions Do not take more than directed. Adults and children 12 years of age and over: take 1 caplet every 4 hours while symptoms persist. Do not use more than 6 caplets in any 24-hour period unless directed by a doctor. Children under 12 years of age: do not use because this product contains too much medication for children under this age.

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Drug Facts (continued)

Drug Facts

Active ingredients (in each caplet)

Ibuprofen 200 mg (NSAID)..... Nasal Decongestant
 Phenylephrine HCl 10 mg..... Nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves these symptoms associated with the common cold or flu:
 - nasal congestion
 - fever
 - sinus pressure
 - headache
 - minor body aches and pains
- temporarily reduces fever
- temporarily reduces nasal breathing through the nose

NDC 436-01-9505

SUDAFED^{PE}

HEAD CONGESTION + PAIN

Ibuprofen 200 mg, Phenylephrine Hydrochloride 10 mg Tablets
 Pain Reliever/Fever Reducer (NSAID),
 Nasal Decongestant

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*CAPSULE-SHAPED TABLETS

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- NASAL CONGESTION
- SINUS PRESSURE
- NASAL SWELLING
- HEADACHE
- FEVER
- BODY ACHES

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ibuprofen and phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-436
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	SUPE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-436-01	2 in 1 CARTON	06/17/2019	
1		10 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
ANDA	ANDA203200	06/17/2019	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.