SINUS PRESSURE AND PAIN PE- acetaminophen and phenylephrine hydrochloride tablet, coated
GOODSENSE

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1120B-GDS-2022-1118

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 upper 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 dosage

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 take 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	

children under 12 years	▪ ask a doctor

Other information

- store between 20-25ºC (68-77ºF) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

GOODSENSE®

NDC 50804-220-06

Maximum Strength

Non-Drowsy

Sinus Pressure + Pain PE

Acetaminophen, Phenylephrine HCl

Pain Reliever / Fever Reducer, Nasal Decongestant

• Sinus Headache

• Sinus Pressure

• Sinus Congestion

24 CAPLETS

Actual Size

Compare to active ingredients of Sudafed PE® Sinus Pressure + Pain†


GOODSENSE®
Maximum Strength
Sinus Pressure + Pain PE
GOODSENSE®
NDC 50804-220-06
Maximum Strength
Non-Drowsy
Sinus Pressure + Pain PE
Acetaminophen, Phenylephrine HCl
Pain Reliever / Fever Reducer, Nasal Decongestant
• Sinus Headache
• Sinus Pressure
• Sinus Congestion
Actual Size
24 CAPLETS
Compare to active ingredients of Sudafed PE® Sinus Pressure + Pain†
NC
NC
NC
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Phenylephrine HCl 5 mg ..... Nasal decongestant
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■ temporarily relieves these symptoms associated with hay fever or other upper 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.
Drug Facts (continued)
■ 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 dosage
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.
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children under 12 years ■ ask a doctor
Drug Facts (continued)
Other information
■ store between 20-25°C (68-77°F) in a dry place
■ retain carton for complete product information and warnings
Inactive ingredients colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone,
Drug Facts (continued)
FD&C yellow #6 aluminum lake, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide
DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN
†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Sinus Pressure + Pain.
Distributed by:
Perrigo Direct, Inc.
Peachtree City, GA 30269
www.PerrigoDirect.com
1-844-705-4384
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SINUS PRESSURE AND PAIN PE

acetaminophen and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50804-220
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	AAA;1120
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804-220-06	2 in 1 CARTON	08/01/2020	
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 final	part341	08/01/2020	

Labeler - GOODSENSE (076059836)

Revised: 11/2022 GOODSENSE