

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

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e0ef968-dff3-4446-8412-8085677332f0>

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**1120B-PRV-2020-0903**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
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	<ul style="list-style-type: none"> <li>▪ take 2 caplets every 4 hours</li> <li>▪ do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>▪ ask a doctor</li> </ul>

**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, 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**

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN SUDAFED PE® SINUS PRESSURE + PAIN†  
NON-DROWSY

MAXIMUM STRENGTH

Sinus Pressure + Pain

Acetaminophen, Phenylephrine HCl

Pain Reliever/Fever Reducer, Nasal Decongestant

Relieves:

- Sinus Pressure & Congestion
- Sinus Headache

ACTUAL SIZE

24 CAPLETS

**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, 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

**Drug Facts (continued)**

**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  
 ■ promotes sinus drainage  
 ■ temporarily reduces fever

**Warnings**  
 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. Other drugs containing acetaminophen or other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product  
 ■ with other drugs containing acetaminophen  
 ■ 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.

**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.

**Major alert**  
 Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away.

**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. Other drugs containing acetaminophen or other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product  
 ■ with other drugs containing acetaminophen  
 ■ 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.

**Directions**  
 ■ take 2 caplets every 4 hours  
 ■ do not take more than 10 caplets in 24 hours  
 children under 12 years ■ ask a doctor  
 adults and children ■ do not take more than directed (see overdose warning)

**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.

**Keep out of reach of children.**  
 If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition:  
 ■ redness or swelling is present  
 ■ fever gets worse or lasts more than 3 days  
 ■ pain or nasal congestion gets worse or lasts more than 7 days  
 ■ nervousness, dizziness, or sleeplessness occur  
 ■ Stop use and ask a doctor if

**When using this product do not exceed recommended dosage**

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

**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)**



**DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN**

This product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Sudafed PE® Sinus Pressure + Pain.

Distributed By:  
 Pharmacy Value Alliance, LLC  
 407 East Lancaster Avenue  
 Wayne, PA 19087

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

**Premier Value®** **MAXIMUM STRENGTH** **NON-DROWSY**  
**Sinus Pressure + Pain**  
 Acetaminophen, Phenylephrine HCl

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Relieves:  
 • Sinus Pressure & Congestion  
 • Sinus Headache

**24 CAPLETS**

ACTUAL SIZE

COMPARE TO THE ACTIVE INGREDIENTS IN SUDAFED PE® SINUS PRESSURE + PAIN

NC

NC

NC



# SINUS PRESSURE AND PAIN

acetaminophen and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-173
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	AAA;1120
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-173-24	2 in 1 CARTON	09/01/2020	04/30/2026
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	09/01/2020	04/30/2026

**Labeler** - <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e0ef968-dff3-4446-8412-8085677332f0> (101668460)

Revised: 10/2024

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e0ef968-dff3-4446-8412-8085677332f0>