

**SINUS PRESSURE PLUS PAIN PE- acetaminophen and phenylephrine hydrochloride tablet, coated**  
**Harris Teeter**

*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.*

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**1120B-HTE-2021-1108**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</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	

Children  
under 12  
years

- ask a doctor

### 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

### PRINCIPAL DISPLAY PANEL

Harris Teeter™

Sinus Pressure + Pain PE

†Compare to the Active Ingredients in Sudafed PE® Sinus Pressure + Pain  
Maximum Strength

Non-Drowsy

Acetaminophen & Phenylephrine HCl

PAIN RELIEVER / FEVER REDUCER, NASAL DECONGESTANT

Relieves

- Sinus Pressure & Congestion
- Sinus Headache

24 CAPLETS

Actual Size

<b>Drug Facts (continued)</b> <b>Other information</b> ■ store between 20-25°C (68-77°F) in a dry place ■ retain carton for complete product information and warnings <b>Inactive ingredients</b> corn starch, croscarmellose sodium, crospovidone, colloidal silicon dioxide,	<b>Drug Facts (continued)</b> 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 <b>Questions or comments?</b> 1-844-705-4384
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<b>Drug Facts</b> <b>Active ingredients (in each caplet)</b> Acetaminophen 325 mg Phenylephrine HCl 5 mg <b>Purpose</b> Pain reliever/fever reducer Nasal decongestant <b>Uses</b> ■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: ■ sinus congestion and pressure ■ minor aches and pains ■ promotes sinus drainage ■ temporarily reduces fever <b>Warnings</b> 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. ■ 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen <b>Allergy alert:</b> 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. <b>Do not use</b> ■ 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.	<b>Drug Facts (continued)</b> ■ 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 ■ trouble urinating due to an enlarged prostate gland ■ thinning drug warfarin <b>When using this product do not exceed recommended dosage</b> 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 If pregnant or breast-feeding, ask a health professional before use. <b>Overdose warning:</b> 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. <b>Directions</b> ■ do not take more than directed (see overdose warning) adults and children ■ take 2 caplets every 4 hours ■ do not take more than 10 caplets in 24 hours children under 12 years ■ ask a doctor
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†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Sinus Pressure + Pain.

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

PROUDLY DISTRIBUTED BY:  
 HARRIS TEETER LLC, MATTHEWS, NC 28105  
**yourplusguarantee.**  
 1-800-432-6111 or harristeeter.com



## Sinus Pressure + Pain PE

**Maximum Strength, Non-Drowsy  
 Acetaminophen & Phenylephrine HCl**



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**Maximum Strength  
 Non-Drowsy  
 Acetaminophen & Phenylephrine HCl**

**PAIN RELIEVER / FEVER REDUCER, NASAL DECONGESTANT**

- Relieves
- Sinus Pressure & Congestion
  - Sinus Headache

**24 CAPLETS**



Actual Size

NC

NC

NC

# SINUS PRESSURE PLUS PAIN PE

acetaminophen and phenylephrine hydrochloride tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-320
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)	
CROSPVIDONE (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: 3WJQ0SDW1A)	
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:72036-320-06	2 in 1 CARTON	06/19/2020	
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	06/19/2020	

**Labeler** - Harris Teeter (047279351)

Revised: 11/2021

Harris Teeter