

**SINUS HEADACHE- 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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**HTE - 1123 - 2019-1011**

***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:
  - headache
  - sinus congestion and pressure
  - nasal congestion
  - minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- 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>• swallow whole – do not crush, chew, or dissolve</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

**Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10, FD&C

blue #1, flavor, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**

1-844-705-4384

**PRINCIPAL DISPLAY PANEL**

Harris Teeter

Sinus & Headache

Compare to the Active Ingredients in Tylenol(R) Sinus + Headache

Daytime, Non-Drowsy

Acetaminophen & Phenylephrine HCl

PAIN RELIEVER/FEVER REDUCER, NASAL DECONGESTANT

Relieves

Sinus Headache

Sinus Pressure

Nasal Congestion

For Adults

24 COOL TASTE CAPLETS

Actual Size

NC

NC

NC

**Drug Facts (continued)**

**Warnings (continued)**

**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 ■ diabetes ■ heart disease ■ thyroid disease ■ high blood pressure ■ trouble urinating due to an enlarged prostate gland

**Directions**

adults and children 12 years and over

■ take 2 caplets every 4 hours

■ swallow whole – do not crush, chew, or dissolve

■ do not take more than 10 caplets in 24 hours

children under 12 years

■ ask a doctor

▲

**Drug Facts (continued)**

**Drug Facts**

**Active ingredients (in each caplet)**

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

Phenylephrine HCl 5 mg.....Nasal decongestant

**Uses**

■ temporarily relieves these symptoms associated with hay fever

■ temporarily reduces fever

■ promotes sinus drainage

■ helps decongest sinus openings and passages

■ helps clear nasal passages

■ minor aches and pains

■ sinus congestion and pressure

■ headache

■ nasal congestion

■ 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 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.

**Stop use and ask a doctor if**

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■ 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.

**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

# Sinus & Headache



## Daytime, Non-Drowsy Acetaminophen & Phenylephrine HCl

PAIN RELIEVER / FEVER REDUCER, NASAL DECONGESTANT

- Relieves
- Sinus Headache
  - Sinus Pressure
  - Nasal Congestion
  - For Adults

### 24 COOL TASTE CAPLETS



Actual Size

**Drug Facts (continued)**

**Other information (continued)**

■ store between 20-25°C (68-77°F) in a dry place

■ retain carton for complete product information

**Drug Facts (continued)**

FD&C blue #1, flavor, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

**Inactive ingredients** acetaminophen potassium, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10.

**Questions or comments?**

1-844-705-4384

**yourplus** guarantee.

1-800-432-6111 or harrisiteeter.com

PROUDLY DISTRIBUTED BY:  
HARRIS TEETER, LLC  
MATTHEWS, NC 28105

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Sinus + Headache.

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



F112305HTE\_R0

acetaminophen and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72036-123
<b>Route of Administration</b>	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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1114
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72036-123-05	2 in 1 CARTON	07/17/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**Labeler** - Harris Teeter (047279351)

Revised: 10/2019

Harris Teeter