

**PRESSURE PAIN COLD- acetaminophen, dextromethorphan hydrobromide, guaifenesin, 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 - 1174 - 2019-1011**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purposes</b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves these symptoms due to the common cold:
  - nasal congestion
  - headache
  - minor aches and pains
  - cough
  - sore throat
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- 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.

### **Sore throat warning**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

**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, nasal congestion, or cough 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
- cough comes back or occurs with rash or headache that lasts

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

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, 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

Pressure & Pain PE & Cold

Compare to the Active Ingredients in Sudafed(R) PE Pressure + Pain + Cold

Acetaminophen, Phenylephrine HCl, Guaifenesin, Dextromethorphan HBr

PAIN RELIEVER/FEVER REDUCER, NASAL DECONGESTANT, EXPECTORANT, COUGH SUPPRESSANT

Relieves

Sinus Pressure & Congestion

Sinus Headache & Sore Throat

Chest Congestion

Cough

For Adults

24 CAPLETS

Actual Size

NC

NC

NC

**Drug Facts (continued)**

**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.  
**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.  
**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

**Drug Facts (continued)**

**Directions** ■ 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 ■ ask a doctor 12 years children under

**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.  
 If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.  
 These could be signs of a serious condition.  
 ■ cough comes back or occurs with rash or headache that lasts ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleeplessness occur ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough that occurs with too much phlegm (mucus)  
**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**  
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ cough comes back or occurs with rash or headache that lasts ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough that occurs with too much phlegm (mucus)  
**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, nasal congestion, or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ cough comes back or occurs with rash or headache that lasts

**Drug Facts**

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**Drug Facts (continued)**

**Uses** ■ temporarily relieves these symptoms due to the common cold: ■ nasal congestion ■ headache ■ minor aches and pains ■ cough ■ sore throat ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive ■ temporarily reduces fever



# Pressure & Pain PE & Cold

## Non-Drowsy

**Acetaminophen, Phenylephrine HCl, Guaifenesin, Dextromethorphan HBr**

**PAIN RELIEVER / FEVER REDUCER, NASAL DECONGESTANT, EXPECTORANT, COUGH SUPPRESSANT**

- Relieves
- Sinus Pressure & Congestion
  - Sinus Headache & Sore Throat
  - Chest Congestion
  - Cough
  - For Adults

**24 CAPLETS**



Actual Size

†Compare to the Active Ingredients in Sudafed PE® Pressure + Pain + Cold



**Drug Facts (continued)**

**Other information**  
 ■ store between 20-25°C (68-77°F) in a dry place  
 ■ retain carton for complete product information

**Drug Facts (continued)**

**Inactive ingredients** colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C yellow #6

**Questions or comments?** 1-844-705-4384

aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

**yourplusguarantee.**  
 1-800-432-6111 or harristeeter.com

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

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

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

# PRESSURE PAIN COLD

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72036-174
<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>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 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</b> (UNII: 2S7830E561)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, PREGELATINIZED 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;1134
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:72036-174-02	2 in 1 CARTON	08/16/2016	09/30/2024
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	08/16/2016	09/30/2024

**Labeler** - Harris Teeter (047279351)

Revised: 9/2022

Harris Teeter