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.

HTE - 1174 - 2019-1011

Drug Facts

Active ingredients (in each caplet)	Purposes
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	 take 2 caplets every 4 hours do not take more than 10 caplets in 24 hours
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

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

 thyroid disease ■ diabetes ■ high blood pressure ■ near disease ■ liver disease Ask a doctor before use if you have

of its ingredients

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 - It you are now taking a prescription monoamine oxidase inhibitor acetaminophen, ask a doctor or pharmacist.
 - nonprescription). If you are not sure whether a drug contains ■ with any other drug containing acetaminophen (prescription or

vomiting, consult a doctor promptly.

qays, is accompanied or followed by fever, headache, rash, nausea, or Sore throat warning: If sore throat is severe, persists for more than 2 If a skin reaction occurs, stop use and seek medical help right away. Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash

- 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen
 - more than 4,000 mg of acetaminophen in 24 hours
 - Severe liver damage may occur if you take
- dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Liver warning: This product contains acetaminophen. The maximum daily **SprinneW**

Drug Facts (continued)

Drug Facts

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If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition.

- cough comes back or occurs with rash or headache that lasts uew symptoms occur ■ redness or swelling is present ■ fever gets worse or lasts more than 3 days ■ pain, nasal congestion, or cough 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

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

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■ trouble urinating due to an enlarged prostate gland Drug Facts (continued)

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Drug Facts (continued)

Nasal decongestant Phenylephrine HCI 5 mg Expectorant Guaifenesin 100 mg.. Cough suppressant Acetaminophen 325 mg..... Active ingredients (in each caplet) Purpose

 nasal congestion common cold: USes • temporarily relieves these symptoms due to the

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



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



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

Actual Size

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

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

Drug Facts (continued)

1-844-705-4384 Questions or comments?

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

Drug Facts (continued)

PRESSURE PAIN COLD

USE IF BLISTER UNITS TORN OR BROKEN

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Syour*plus*guarantee. PROUDLY DISTRIBUTED BY: Harris Teeter, LLC Matthews, NC 28105 acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-174
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;1134
Contains			

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

Labeler - Harris Teeter (047279351)

Revised: 10/2019 Harris Teeter