

PRESSURE PAIN MUCUS PE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Chain Drug Marketing Association

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.

1173 - QCH - 2014-1030

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Guaifenesin 200 mg	Expectorant
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
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus 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

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"> ▪ take 2 caplets every 4 hours ▪ do not take more than 10 caplets in 24 hours
children under 12 years	<ul style="list-style-type: none"> ▪ 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, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 63868-747-24

QUALITY CHOICE

†Compare to Active Ingredients in SUDAFED PE® Pressure + Pain + Mucus

Pressure + Pain + Mucus PE

Pain Reliever / Fever Reducer, Nasal Decongestant, Expectorant

Acetaminophen, Phenylephrine HCl, Guaifenesin

For Relief of:

Sinus Headache

Sinus Pressure & Congestion

Chest Congestion

24 Caplets

NC

NC

NC

Drug Facts (continued)

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. With other drugs containing acetaminophen 3 or more alcoholic drinks every day while using 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.
- 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 thyroid disease diabetes high blood pressure

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)

Directions
 adults and children 12 years and over take 2 caplets every 4 hours do not take more than 10 caplets in 24 hours ask a doctor children under 12 years

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.

- cough comes back or occurs with rash or headache that lasts new symptoms occur
- redness or swelling is present
- fever gets worse or lasts more than 3 days than 7 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 blood thinning drug warfarin

Drug Facts (continued)
 Ask a doctor or pharmacist before use if you are taking the

Drug Facts
 temporarily relieves these symptoms associated with

Uses

Active ingredients (in each caplet) Purpose
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 Guaifenesin 200 mg Expectorant
 Phenylephrine HCl 5 mg Nasal decongestant

Drug Facts (continued)
 may fever or other upper respiratory allergies, and the common cold: sinus congestion and pressure headache minor aches and pains nasal congestion helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive



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NDC 63866-747-24

Compare to Active Ingredients in SUDAFED® Pressure + Pain + Mucus

Non-Drowsy Pressure + Pain + Mucus PE

Pain Reliever | Fever Reducer, Nasal Decongestant, Expectorant

Acetaminophen, Phenylephrine HCl, Guaifenesin

For Relief of:
 Sinus Headache
 Sinus Pressure & Congestion
 Chest Congestion



24 Caplets

Drug Facts (continued)
 retain carton for complete product information store between 20-25°C (68-77°F) in a dry place

Inactive ingredients
 croscarmellose sodium, crospovidone, colloidal silicon dioxide, talc, titanium dioxide

Drug Facts (continued)
 mattedextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Distributed by C.D.M.A., Inc.®
 4357 W. Nine Mile
 Novi, MI 48376-0995
 www.cdma.com
 Questions: 248-446-9300



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

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

F1173020CH_R0

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-747
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	AAA;1173
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-747-24	2 in 1 CARTON	05/21/2014	
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
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Labeler - Chain Drug Marketing Association (011920774)

Revised: 12/2018

Chain Drug Marketing Association