

HEAD CONGESTION MUCUS PE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
CHAIN DRUG MARKETING ASSOCIATION INC

1173-QCH-2022-0803

Drug Facts

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

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
- 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	▪ take 2 caplets every 4 hours
children	▪ do not take more than 10

12 years and over	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 and warnings

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

Quality Choice®

NDC 63868-103-24

†Compare to Active Ingredients in SUDAFED PE® Head Congestion + Mucus

Head Congestion + Mucus PE

Acetaminophen, Guaifenesin, Phenylephrine HCl

Pain Reliever | Fever Reducer, Expectorant, Nasal Decongestant

For Relief of:

Sinus Pressure

Headache

Chest Congestion

Non-Drowsy

Actual Size

24 CAPLETS



Drug Facts (continued)

Other information

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

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, colloidal silicon dioxide

Drug Facts (continued)

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

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

■ 3 or more alcoholic drinks every day while using this product

■ with other drugs containing acetaminophen

Allergy alert: 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.

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 the 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 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

■ cough that occurs with too much phlegm (mucus)

Drug Facts (continued)

Directions

do not take more than directed (see overdose warning)

adults and children 12 years and over	■ take 2 caplets every 4 hours
children under 12 years	■ ask a doctor

■ do not take more than 10 caplets in 24 hours

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
- 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

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

Drug Facts

Active ingredients (in each caplet)

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

Guaifenesin 200 mg.....Expectorant

Phenylephrine HCl 5 mg.....Nasal decongestant

Purpose

temporarily relieves these symptoms associated with

Drug Facts (continued)

may fever or other upper respiratory allergies, and the common cold:

- sinus congestion and pressure
- headache
- nasal congestion
- minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

■ temporarily reduces fever

NDC 63868-103-24



Compare to Active Ingredients in SUDAFED PE®

Head Congestion + Mucus

Head Congestion + Mucus PE

Acetaminophen, Guaifenesin, Phenylephrine HCl

Pain Reliever | Fever Reducer, Expectorant, Nasal Decongestant

For Relief of:

Sinus Pressure Headache
Chest Congestion

Actual Size



24 CAPLETS

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Head Congestion + Mucus.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN



Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

HEAD CONGESTION MUCUS PE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-103
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	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED 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:63868-103-24	2 in 1 CARTON	08/03/2022	
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 Drug	M012	08/03/2022	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 12/2024

CHAIN DRUG MARKETING ASSOCIATION INC