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

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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#### 1173-QCH-2022-0803

#### **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

#### 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 children 12 years and over	<ul> <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><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 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

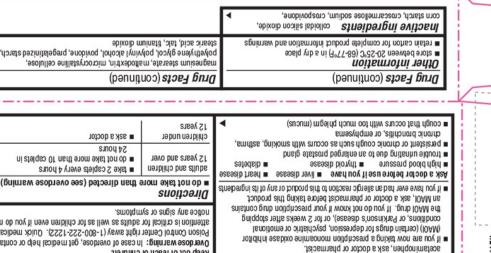
Headache

**Chest Congestion** 

Non-Drowsy

**Actual Size** 

24 CAPLETS



nonprescription). If you are not sure whether a drug contains ■ with any other drug containing acetaminophen (prescription or

If a skin reaction occurs, stop use and seek medical help right away. Symptoms may include: 

skin reddening 

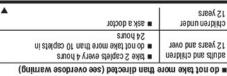
blisters 

rash Allergy alert. Acetaminophen may cause severe skin reactions. 2 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

**Drug Facts** (continued)



attention is critical for adults as well as for children even if you do not Poison Control Center right away (1-800-222-1222). Quick medical Overdose warning: In case of overdose, get medical help or contact a keep out of reach of children. If pregnant or breast-feeding, ask a health professional before use.

L nese could be signs of a senous 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 ■ Dervousness, dizziness, or sleeplessness occur
  - Stop use and ask a doctor if

When using this product do not exceed recommended dosage Trinning arug warrarin

yak a doctor or pharmacist before use if you are taking the blood

**Drug Facts** (continued)

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Nasal decongestant Роспутербите нСт 5 mg. Expectorant Guaifenesin 200 mg. Purpose Active ingredients (in each caplet)

NSGS = temporarily relieves these symptoms associated with

Drug Facts

NDC 63868-103-24

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

## **Head Congestion + Mucus PE**

Acetaminophen, Guaifenesin, Phenylephrine HCI

Pain Reliever | Fever Reducer, Expectorant, **Nasal Decongestant** 

For Relief of:

Sinus Pressure Headache Chest Congestion

**Actual Size** 

Non-Drowsy

24 CAPLETS

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

PE®

260 FACTION

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

CLARANTE OU

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

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### **HEAD CONGESTION MUCUS PE**

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

<b>Product Information</b>			
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: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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: M280L1HH48)	
CROSPOVIDONE (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: 08232NY3SJ)	
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			

P	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				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part341	08/03/2022			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 8/2022 CHAIN DRUG MARKETING ASSOCIATION INC