

# HEAD CONGESTION MUCUS PE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated GOODSENSE

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**1173-GDS-2022-0803**

## **Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
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)**

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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**

GOODSENSE®

NDC 50804-173-02

Non-Drowsy

Head Congestion + Mucus PE

Acetaminophen, Guaifenesin, Phenylephrine HCl

Pain Reliever / Fever Reducer, Expectorant, Nasal Decongestant

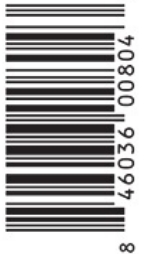
For Relief of

- Sinus Pressure
- Headache
- Chest Congestion

Actual Size

24 CAPLETS

Compare to active ingredients of Sudafed PE® Head Congestion + Mucus†



F117302GDS\_R1



**Drug Facts (continued)**

**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,

**Drug Facts (continued)**

**Drug Facts (continued)**

magnesium stearate, maltoedextrin, 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

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 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 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)

**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

children under 12 years

- ask a doctor

**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.

**Do not use**

- if pregnant or breast-feeding, ask a health professional 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**

- 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.

**Drug Facts (continued)**

**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 have 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

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

Distributed by:  
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Peachtree City, GA 30269  
www.PerrigoDirect.com  
1-844-705-4384  
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**GOODSENSE®** NDC 50804-173-02

**Non-Drowsy**

# Head Congestion + Mucus PE

**Acetaminophen, Guaifenesin, Phenylephrine HCl**  
Pain Reliever / Fever Reducer, Expectorant, Nasal Decongestant

- For Relief of**
- Sinus Pressure
  - Headache
  - Chest Congestion



**24 CAPLETS**

Compare to active ingredients of **Sudafed PE® Head Congestion + Mucus†**

NC

NC

NC

# HEAD CONGESTION MUCUS PE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50804-173
<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>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<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>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	AAA;1173
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804-173-02	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** - GOODSENSE (076059836)

Revised: 10/2024

GOODSENSE