

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

## HEB

*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-HEB-2023-0414**

### **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)**

adults and children 12 years and over	<ul style="list-style-type: none"> <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 style="list-style-type: none"> <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

### Questions or comments?

1-844-705-4384

### PRINCIPAL DISPLAY PANEL

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

NDC 37808-273-02

Head Congestion + Mucus PE

Acetaminophen / Pain Reliever/Fever Reducer

Guaifenesin / Expectorant

Phenylephrine HCl / NAsal Decongestant

For Relief of:

- Sinus Pressure • Headache
- Chest Congestion

Actual Size

24 CAPLETS

<b>Drug Facts (continued)</b> <b>Other information</b> ■ store between 20°-25°C (68°-77°F) in a dry place ■ retain carton for complete product information and warnings <b>Inactive ingredients</b> colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone,	<b>Drug Facts (continued)</b> <b>Questions or comments?</b> 1-844-705-4384 magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide
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<b>Drug Facts (continued)</b> <b>Warnings</b> 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 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 ■ 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)	<b>Drug Facts (continued)</b> <b>Directions</b> ■ 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 ■ ask a doctor children under 12 years notice any signs or symptoms. attention is critical for adults as well as for children even if you do not overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical help is critical for adults as well as for children even if you do not 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 sleepiness 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
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†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**

**100% GUARANTEE**

**H-E-B**

If you aren't completely satisfied with this product, we'll be happy to replace it or refund your money. You have our word on it.

**pharmacie**

DISTRIBUTED BY H-E-B®  
SAN ANTONIO, TX 78204

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

**H-E-B**

NDC 37808-273-02

# Head Congestion + Mucus PE


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

**For Relief of:**

- Sinus Pressure
- Headache
- Chest Congestion

**24 CAPLETS**

Actual Size



# HEAD CONGESTION PLUS MUCUS PE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-273
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:37808-273-02	2 in 1 CARTON	04/14/2023	
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	04/14/2023	

**Labeler** - HEB (007924756)

Revised: 4/2023

HEB