

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

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**1173-TCR-2022-1214**

## **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**

NDC 36800-793-02

TopCare® health

COMPARE TO SUDAFED PE® HEAD CONGESTION + MUCUS ACTIVE INGREDIENTS†

NON-DROWSY

Head Congestion + Mucus PE

ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER

GUAIFENESIN - EXPECTORANT

PHENYLEPHRINE HCl - NASAL DECONGESTANT

RELIEF OF: • Sinus Pressure • Headache • Chest Congestion

24 CAPLETS

actual size

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

**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, croscopolvone,

**Drug Facts (continued)**

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

**Drug Facts (continued)**

**Warnings**

**Liver 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

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash

**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)

**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

12 years and over ■ do not take more than 10 caplets in 24 hours

children under 12 years ■ ask a doctor

**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
- nervousness, dizziness, or sleeplessness occur
- nausea, nasal congestion, or cough gets worse or lasts more than 7 days

**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 (continued)**

**Uses**

- temporarily relieves these symptoms associated with

**Active ingredients (in each caplet)**

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

Guaifenesin 200 mg.....Expectorant

Phenylephrine HCl 5 mg.....Nasal decongestant

**Drug Facts (continued)**

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



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QUALITY GUARANTEED

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



COMPARE TO SUDAFED PE® HEAD CONGESTION + MUCUS ACTIVE INGREDIENTS†

NON-DROWSY

# Head Congestion + Mucus PE

ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER  
GUAIFENESIN - EXPECTORANT  
PHENYLEPHRINE HCl - NASAL DECONGESTANT

RELIEF OF: • Sinus Pressure • Headache • Chest Congestion

24 CAPLETS

actual size

NC

NC

NC

NDC 36800-793-02

# HEAD CONGESTION PLUS MUCUS PE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-793
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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 HYDROCHLORIDE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE 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

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:36800-793-02	2 in 1 CARTON	04/26/2021	
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	04/26/2021	

**Labeler** - TOPCARE (006935977)

Revised: 12/2024

TOPCARE