**PRESSURE PLUS PAIN PE PLUS COLD- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated**
**TopCo Associates LLC**

*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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**TCR - 1174 - 2019-1016**

***Drug Facts***

| ***Active ingredients (in each caplet)*** | ***Purposes*** |
|---|---|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Guaifenesin 100 mg | Expectorant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

**Uses**

- temporarily relieves these symptoms due to the common cold:
  - nasal congestion
  - headache
  - minor aches and pains
  - cough
  - sore throat
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes 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.

**Sore throat warning**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**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 | ▪ take 2 caplets every 4 hours<br>▪ do not take more than 10 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

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

**PRINCIPAL DISPLAY PANEL**

NDC 36800-775-02

TopCare® Health™

Compare to Sudafed PE® Pressure + Pain + Cold Active Ingredients*

Non-Drowsy

Pressure + Pain PE + Cold

Acetaminophen - Pain Reliever/Fever Reducer

Phenylephrine HCl – Nasal Decongestant

Guaifenesin – Expectorant

Dextromethorphan HBr – Cough Suppressant

Relief of:

Sinus Pressure + Congestion

Sinus Headache • Sore Throat • Chest Congestion • Cough

Pharmacists Recommend

24 Caplets

For Adults


Drug Facts
Active ingredients (in each caplet) Purpose
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Phenylephrine HCl 5 mg Nasal decongestant
Uses
temporarily relieves these symptoms due to the common cold:
nasal congestion
headache
minor aches and pains
cough
sore throat
helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes 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.
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.
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
Drug Facts (continued)
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: take 2 caplets every 4 hours; do not take more than 10 caplets in 24 hours
children under 12 years: ask a doctor
Drug Facts (continued)
Other information
store between 20-25°C (68-77°F) in a dry place
retain carton for complete product information
Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide
DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN
This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Pressure + Pain + Cold.
DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 © TOPCO ASSOCIATES LLC QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com
This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.
F117402TCR_R1
0 36800 43779 1
NDC 36800-775-02
TopCare® health™
COMPARE TO SUDAFED PE® PRESSURE + PAIN + COLD ACTIVE INGREDIENTS*
NON-DROWSY
Pressure + Pain PE + Cold
ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER
PHENYLEPHRINE HCl - NASAL DECONGESTANT, GUAIFENESIN - EXPECTORANT
DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT
RELIEF OF: • Sinus Pressure + Congestion
• Sinus Headache • Sore Throat • Chest Congestion • Cough
PHARMACISTS RECOMMEND
24 CAPLETS
For Adults
actual size
NC
NC
NC

# PRESSURE PLUS PAIN PE PLUS COLD

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:36800-775 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **CROSPOVIDONE** (UNII: 2S7830E561) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **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** | orange | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | AAA;1134 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| **1** | NDC:36800-775-02 | 2 in 1 CARTON | 06/30/2017 | 06/30/2024 |
| **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 | 06/30/2017 | 06/30/2024 |

## Labeler - TopCo Associates LLC (006935977)

Revised: 5/2022 TopCo Associates LLC