

PRESSURE PAIN COLD- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated
Harmon Stores 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.

HAR - 1174 - 2019-1009

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 | <ul style="list-style-type: none">▪ take 2 caplets every 4 hours▪ do not take more than 10 caplets in 24 hours |
| children under 12 years | <ul style="list-style-type: none">▪ 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

CORE VALUES

Compare to the active ingredients in Sudafed PE® Pressure + Pain + Cold

NON-DROWSY

Pressure+Pain+Cold Relief

for Adults

Acetaminophen, Phenylephrine HCl, Guaifenesin, Dextromethorphan HBr

Pain Reliever / Fever Reducer, Nasal Decongestant, Expectorant, Cough Suppressant

For relief of:

Sinus Pressure + Congestion, Chest Congestion

Sinus Headache, Cough

Sore Throat

Actual Size

24 CAPLETS



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Drug Facts (continued)
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Drug Facts (continued)
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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. ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ sore throat ■ fever ■ rash ■ if a skin reaction occurs, stop use and seek medical help right away. ■ 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 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
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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 ■ 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 sleeplessness occur
Stop use and ask a doctor if
 ■ 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)
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CORE VALUES™ Compare to active ingredients in Sudafed PE® Pressure + Pain + Cold*

NON-DROWSY Pressure+Pain+Cold Relief for Adults

Acetaminophen, Phenylephrine HCl, Guaifenesin, Dextromethorphan HBr Pain Reliever / Fever Reducer, Nasal Decongestant, Expectorant, Cough Suppressant

- For relief of:
- Sinus Pressure + Congestion
 - Sinus Headache
 - Sore Throat
 - Chest Congestion
 - Cough



Actual Size

24 CAPLETS

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

SATISFACTION GUARANTEED Or Your Money Back

Distributed by Liberty Procurement Co. Inc. 650 Liberty Ave. Union, NJ 07083 USA Visit us at: www.facevalues.com

*This product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Sudafed PE® Pressure + Pain + Cold.

NC

NC

NC

PRESSURE PAIN COLD

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

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63940-340 |
| 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) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| CROSPVIDONE (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:63940-340-02 | 2 in 1 CARTON | 09/11/2018 | 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 | 09/11/2018 | 06/30/2024 |

Labeler - Harmon Stores Inc. (804085293)

Revised: 8/2022

Harmon Stores Inc.