

**COLD PLUS HEAD CONGESTION SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated**  
**HYVEE INC**

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**1175-HYV-2025-1103**

***Drug Facts***

| <b><i>Active ingredients (in each caplet)</i></b> | <b><i>Purpose</i></b>       |
|---------------------------------------------------|-----------------------------|
| Acetaminophen 325 mg                              | Pain reliever/fever reducer |
| Guaifenesin 200 mg                                | Expectorant                 |
| Phenylephrine HCl 5 mg                            | Nasal decongestant          |

**Uses**

- for the temporary relief of the following cold symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to 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"><li>▪ take 2 caplets every 4 hours</li><li>▪ swallow whole – do not crush, chew, or dissolve</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**

acesulfame potassium, colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

### **Questions or comments?**

1-844-705-4384

### **PRINCIPAL DISPLAY PANEL**

HyVee®

NDC 42507-375-02

\*Compare to the Active Ingredients in Tylenol® Cold + Head Congestion Severe

For Adults

Cold + Head Congestion Severe

Acetaminophen, Phenylephrine HCl, Guaifenesin

Pain Reliever/Fever Reducer,

Nasal Decongestant,

Expectorant

For Relief of:

- Headache + Body Aches
- Fever + Sore Throat

- Nasal Congestion
  - Mucus + Chest Congetion
- 24 COOL TASTE CAPLETS



COLD PLUS HEAD CONGESTION SEVERE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

| Product Information                                                              |                |                             |               |
|----------------------------------------------------------------------------------|----------------|-----------------------------|---------------|
| Product Type                                                                     | HUMAN OTC DRUG | Item Code (Source)          | NDC:42507-375 |
| 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 HYDROCHLORIDE | 5 mg          |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|-----------------------------------------------------|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)             |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                  |          |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48)             |          |
| CROSPVIDONE (UNII: 2S7830E561)                      |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)               |          |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)                     |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)      |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| POLYVINYL ALCOHOL (UNII: 532B59J990)                |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)            |          |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)      |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                 |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                     |          |
| TALC (UNII: 7SEV7J4R1U)                             |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                 |          |

## Product Characteristics

|          |       |              |          |
|----------|-------|--------------|----------|
| Color    | white | Score        | no score |
| Shape    | OVAL  | Size         | 19mm     |
| Flavor   | MINT  | Imprint Code | AAA;1119 |
| Contains |       |              |          |

## Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:42507-375-02 | 2 in 1 CARTON                                           | 11/03/2025           |                    |
| 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                                     | 11/03/2025           |                    |

**Labeler** - HYVEE INC (006925671)