

**MUCUS RELIEF COLD AND FLU ALL IN ONE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated**  
**CHAIN DRUG CONSORTIUM**

*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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**PRV-1198-2020-1204**

**Drug Facts**

| <b>Active ingredients (in each caplet)</b> | <b>Purpose</b>              |
|--|-----------------------------|
| Acetaminophen 325 mg                       | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg                 | Cough suppressant           |
| Guaifenesin 200 mg                         | Expectorant                 |
| Phenylephrine HCl 5 mg                     | Nasal decongestant          |

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - nasal congestion
  - headache
  - cough
  - minor aches and pains
  - sore throat
  - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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.

### **Ask a doctor before use if you have**

- liver disease
- heart disease
- diabetes
- 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)

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

### **When using this product do not use more than directed**

### **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**

Taking more than the recommended dose (overdose) may cause liver damage. 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)**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

### **Other information**

- store between 20-25°C (68-77°F) in a dry place

### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, 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**

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN MUCINEX® FAST-MAX® COLD & FLU ALL IN ONE

For Ages 12+

MAXIMUM STRENGTH

MUCUS RELIEF COLD & FLU ALL-IN-ONE

Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl

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

For Relief of:

- Headache, Body Pain, Sore Throat & Fever
- Cough & Chest Congestion
- Nasal Congestion
- Sinus Congestion & Sinus Pressure

Actual Size

20 CAPLETS



## MUCUS RELIEF COLD AND FLU ALL IN ONE

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

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68016-625 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength             | Strength |
|--|-------------------------------|----------|
| <b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                    | ACETAMINOPHEN                 | 325 mg   |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 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

| Ingredient Name  | Strength |
|--|----------|
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                  |          |
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)             |          |
| <b>CROSPROVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)       |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)              |          |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)                   |          |
| <b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)            |          |
| <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, 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>    | red  | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL | <b>Size</b>         | 19mm     |
| <b>Flavor</b>   |      | <b>Imprint Code</b> | AAA;1165 |
| <b>Contains</b> |      |                     |          |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68016-625-20 | 2 in 1 CARTON   | 12/01/2020           |                    |
| 1 |                  | 10 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                                  | 12/01/2020           |                    |

**Labeler** - CHAIN DRUG CONSORTIUM (101668460)