

**COLD FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated**  
**STRATEGIC SOURCING SERVICES 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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**HMT - 1163 - 2020-0603**

**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**

- for the temporary relief of the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - cough
- 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

### Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

### PRINCIPAL DISPLAY PANEL

#### ***HealthMart(R)***

NDC 62011-0442-1

Compare to Tylenol(R) Cold + FLu Severe active ingredients

FOR ADULTS

Cold + Flu Severe

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

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

For Relief of:

Head + Body Aches

Fever + Sore Throat

Cough + Nasal Congestion

Mucus + Chest Congestion

ACTUAL SIZE

24 COOL TASTE CAPLETS



**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**

acetylsalicylic acid, croscarmellose sodium, crospovidone, D&C yellow #10, silicon dioxide

**Drug Facts (continued)**

aluminum lake, FD&C blue #2 aluminum lake, favaor, magnesium stearate, malto-dextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polydextrose, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide, polydextrose

**Drug Facts (continued)**

**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

5 or more alcoholic drinks every day while using this product

Always 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.

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

Do not use

- with any other drug containing acetaminophen (prescription or non-prescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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

trouble urinating due to an enlarged prostate gland

**Drug Facts (continued)**

**Directions**

do not take more than directed (see overdose warning)

|                                       |  |
|---------------------------------------|--|
| adults and children 12 years and over | take 2 caplets every 4 hours                 |
| children 6 to 11 years                | 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:

- redness or swelling is present
- fever gets worse or lasts more than 3 days
- skin, nasal congestion, or cough gets worse or lasts more than 7 days
- nausea, dizziness, or sleeplessness occur

Stop use and ask a doctor if

- When using this product do not exceed recommended dosage
- when taking other drugs
- if you are taking the blood thinning drug warfarin

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

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**

**Drug Facts**

**Active ingredients (in each caplet) Purpose**

- Acetaminophen 325 mg: Pain reliever/fever reducer
- Dextromethorphan HBr 10 mg: Cough suppressant
- Guaifenesin 200 mg: Expectorant
- Phenylephrine HCl 5 mg: Nasal decongestant

**Drug Facts (continued)**

**Uses**

- for the temporary relief of the following cold/flu symptoms: minor aches and pains, headache, sore throat
- nasal congestion
- cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

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

**MEKESON**

Another Quality Product Distributed by McKesson Healthcare, distributor of Tylenol® Cold + Flu Severe.

6555 Santa Highway 161 Irving, TX 75039  
Money Back Guarantee  
healthmart.com

NDC 62011-0442-1

Compare to Tylenol® Cold + Flu Severe active ingredients †

**FOR ADULTS**

# Cold + Flu Severe

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



ACTUAL SIZE

**24 COOL TASTE CAPLETS**

For Relief of:

- Head + Body Aches
- Fever + Sore Throat
- Cough + Nasal Congestion
- Mucus + Chest Congestion

NC

NC

NC

# COLD FLU SEVERE

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

## Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:62011-0442 |
| <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>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)             |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                  |          |
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)             |          |
| <b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)         |          |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)            |          |
| <b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)                   |          |
| <b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)              |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)               |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                     |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)      |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A) |          |
| <b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)   |          |
| <b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)            |          |
| <b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)      |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                 |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                     |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                             |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                 |          |

## Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | yellow | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL   | <b>Size</b>         | 19mm     |
| <b>Flavor</b>   | MINT   | <b>Imprint Code</b> | AAA;1136 |
| <b>Contains</b> |        |                     |          |

**Packaging**

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:62011-0442-1 | 2 in 1 CARTON   | 06/03/2020           | 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                                  | 06/03/2020           | 06/30/2024         |

**Labeler** - STRATEGIC SOURCING SERVICES LLC (116956644)

Revised: 11/2022

STRATEGIC SOURCING SERVICES LLC