COLD AND FLU SEVERE- 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.

PRV-1163-2020-0901

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 |

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 | take 2 caplets every 4 hours swallow whole – do not crush, chew, or dissolve 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

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

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® COLD + FLU SEVERE

FOR ADULTS

Cold & Flu Severe

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin

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

Relieves:

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

ACTUAL SIZE

24 COOL TASTE CAPLETS

silicon dioxide, croscamellose sodium, crospovidone, D&C yellow #10 ▶ acesulfame potassium, colloidal thactive ingredients

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> > **Drug Facts** (continued)

1-844-705-4384 Questions or comments?

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Drug Facts (continued)

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Drug Facts (continued)



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Drug Facts (continued)

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Drug Facts (continued)

COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® COLD + FLU SEVERET

FOR ADULTS





Cold & Flu Severe

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin

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

ACTUAL SIZE

Relieves:

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



24 GOOL TASTE GAPLETS

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol[®] Cold + Flu Severe.

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue
Wayne, PA 19087

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

f for any reason you are not satisfied with is product, please return it to the store here purchased for a full refund.

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

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68016-512 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN | 325 mg | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg | |
| PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| SILICON DIO XIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | |
| CROSPOVIDONE (UNII: 2S7830E561) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) | |
| CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL (UNII: 532B59J990) | |
| PO VIDO NE, UNSPECIFIED (UNII: FZ989 GH94E) | |
| STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | yello w | Score | no score |
| Shape | OVAL | Size | 19 mm |
| Flavor | MINT | Imprint Code | AAA;1136 |
| Contains | | | |

| Pack | aging | | | |
|------|-----------|---------------------|-----------------------------|--------------------|
| #] | Item Code | Package Description | Marketing Start Date | Marketing End Date |

| 1 NDC:68016-512-24 | 2 in 1 CARTON | 08/01/2012 | | |
|-----------------------|--|---------------------------------|--------------------|--|
| 1 | 12 in 1 BLISTER PACK; Type 0: Not a Combination Produc | t | | |
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| Maybeting Information | | | | |
| Maulzating Inf | Cormation | | | |
| Marketing Inf | ormation | | | |
| Marketing Info | | Marketing Start Date | Marketing End Date | |
| | y Application Number or Monograph Citation | Marketing Start Date 08/01/2012 | Marketing End Date | |

Labeler - CHAIN DRUG CONSORTIUM (101668460)

Revised: 9/2020 CHAIN DRUG CONSORTIUM