

TYLENOL COLD PLUS FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated
JC World Bell Wholesale Co., Inc.

Tylenol Cold Plus Flu Severe

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

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

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 **Liver warning:**

acetaminophen may cause severe skin reactions. Symptoms may include: **Allergy alert:**

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. **Sore throat**

warning:

- 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

- skin reddening
- blisters
- rash
- If a skin reaction occurs, stop use and seek medical help right away.

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 dose

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.

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. **Overdose warning:**

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• 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

- sodium 3 mg **each caplet contains:**
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or if blister unit is broken**

Inactive ingredients

carnauba wax, croscarmellose sodium, D&C yellow no. 10 aluminum lake, flavor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, sucralose, titanium dioxide

Questions or comments?

call (toll-free) or (collect) **1-877-895-3665215-273-8755**

Package Labeling:

How can we help?
1-877-895-3665



Drug Facts	Drug Facts (continued)
<p>Active ingredients (in each caplet)</p> <p>Acetaminophen 325 mg Pain Reliever</p> <p>Dextromethorphan HBr 10 mg Cough Suppressant</p> <p>Guaifenesin 200 mg Expectorant</p> <p>Phenylephrine HCl 5 mg Nasal Decongestant</p>	<p>Purpose</p> <p>Relieves or reduces pain from the common cold, flu, or other conditions that cause pain.</p> <p>Relieves or reduces coughing.</p> <p>Relieves or reduces nasal congestion.</p> <p>Relieves or reduces the stuffiness of the nose.</p>
<p>Uses</p> <p>For the temporary relief of the following cold/flu symptoms:</p> <ul style="list-style-type: none"> • sore throat • headache • runny nose • nasal congestion • cough • stuffiness of the nose <p>Multiple doses (pharmacologic) and the bronchodilator effect may cause more productive coughing.</p>	<p>Warnings</p> <p>Do not take more than directed (see directions for use).</p> <p>Do not take more than directed (see directions for use).</p> <p>Do not take more than directed (see directions for use).</p>
<p>Directions</p> <p>Adults and children 12 years and older: 2 caplets every 4 to 6 hours as needed. Do not take more than 6 caplets in 24 hours.</p> <p>Children under 12 years: Ask a doctor.</p>	<p>Other information</p> <p>Each caplet contains acetaminophen 325 mg, dextromethorphan hydrobromide 10 mg, guaifenesin 200 mg, and phenylephrine hydrochloride 5 mg.</p>

TYLENOL
COLD + FLU SEVERE
FOR ADULTS
Acetaminophen Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin
Pain Reliever-Fever Reducer, Cough Suppressant, Nasal Decongestant, Expectorant

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TO OPEN PUSH IN TAB AND PULL OUT

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JC World Bell Wholesale Company, Inc. Hackensack, NJ 07601



25 Pouches of 2 Caplets each

TYLENOL COLD PLUS FLU SEVERE

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50269-402(NDC:50580-402)
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	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients		Strength
Ingredient Name		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)		

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	TYLENOL;SEVERE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-402-25	25 in 1 BOX	09/20/2018	
1		2 in 1 POUCH; 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	09/20/2018	

Labeler - JC World Bell Wholesale Co., Inc. (805257581)

Establishment

Name	Address	ID/FEI	Business Operations
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-402)

Establishment

Name	Address	ID/FEI	Business Operations
Kenvue Brands LLC		878046358	manufacture(50269-402)

Revised: 12/2024

JC World Bell Wholesale Co., Inc.