

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

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**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)**

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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	ask a doctor

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**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:**



<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<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>		<b>Imprint Code</b>	TYLENOL;SEVERE
<b>Contains</b>			

### 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
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division		878046358	manufacture(50269-402)

Revised: 11/2023

JC World Bell Wholesale Co., Inc.