

**TYLENOL EXTRA STRENGTH- acetaminophen tablet, film coated**  
**JC World Bell Wholesale Co., Inc.**

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**Tylenol Extra Strength**

***Drug Facts***

***Active ingredient (in each caplet)***

Acetaminophen 500 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
- the common cold
- headache
- backache
- minor pain of arthritis
- toothache
- muscular aches
- premenstrual and menstrual cramps
- temporarily reduces fever

***Warnings***

This product contains acetaminophen. Severe liver damage may occur if you take **Liver warning:**

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

If a skin reaction occurs, stop use and seek medical help right away.

- 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

***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 allergic to acetaminophen or any of the inactive ingredients in this product

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

liver disease

**Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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 6 hours while symptoms last</li><li>• do not take more than 6 caplets in 24 hours, unless directed by a doctor</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	ask a doctor

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**Other information**

- store between 20-25°C (68-77°F)
- **do not use if pouch is torn or damaged**

**Inactive ingredients**

carnauba wax\*, corn starch\*, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, modified starch\*, polyethylene glycol\*, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

\*contains one or more of these ingredients

## Questions or comments?

call (toll-free) or (collect) **1-877-895-3665** or **215-273-8755**

## Package Labeling:

**Drug Facts**

**Active ingredient (in each caplet)** Purpose  
**Acetaminophen 500 mg** Pain reliever/fever reducer

**Uses**  
 ■ temporarily relieve minor aches and pains due to:  
 ■ the common cold ■ headache  
 ■ backache ■ minor pain of arthritis  
 ■ toothache ■ muscular aches  
 ■ menstrual and menstrual cramps  
 ■ temporarily reduce fever

**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:  
 ■ more than 4,000 mg of acetaminophen in 24 hours  
 ■ with other drugs containing acetaminophen  
 ■ 2 or more alcoholic drinks every day while using this product  
**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:  
 ■ skin redness ■ hives ■ rash  
 If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**  
 ■ with any other drug containing acetaminophen (acetaminophen or paracetamol). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.  
 ■ if you are allergic to acetaminophen or any of the inactive ingredients in this product.

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

**Stop use and ask a doctor if:**  
 ■ pain gets worse or lasts more than 10 days  
 ■ fever gets worse or lasts more than 3 days  
 ■ new symptoms occur  
 ■ nausea or swelling is present  
 These could be signs of a serious condition.

**Drug Facts (continued)**  
 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. (1-800-232-3222) 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 ■ take 2 caplets every 6 hours while symptoms and last  
 children ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor  
 (2 years and over) ■ do not use for more than 10 days unless directed by a doctor  
 children under 12 years ■ ask a doctor

**Other information**  
 ■ store between 20-25°C (68-77°F)  
 ■ do not use if granules are broken or damaged

**Inactive ingredients**  
 carnauba wax, corn starch, FD&C red no. 40 aluminum lake, hydroxytoluene, magnesium stearate, modified starch, polyethylene glycol, powdered cellulose, pregelatinized starch, propylene glycol, dibasic sodium starch glycolate, titanium dioxide  
 Contains one or more of these ingredients

**Questions or comments?**  
 call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

**Care To Recycle**

TYLENOL EXTRA STRENGTH			
acetaminophen tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50269-449(NDC:50580-449)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg
Inactive Ingredients			
Ingredient Name			Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)			
STARCH, CORN (UNII: O8232NY3S)			

<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	TYLENOL;500
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-449-25	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	M013	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(50269-449)

### Establishment

Name	Address	ID/FEI	Business Operations
McNeil Healthcare LLC		831188763	manufacture(50269-449)

Revised: 11/2023

JC World Bell Wholesale Co., Inc.