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

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#### Tylenol Extra Strength 1's Blister Pack

#### **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)

adults and children 12 years and over	<ul> <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

#### 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

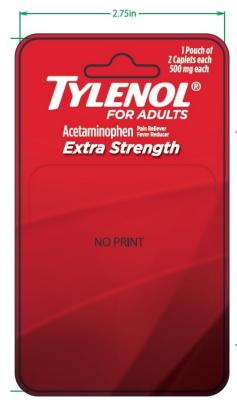
\*contains one or more of these ingredients

#### **Questions or comments?**

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

#### **Package Labeling:**

**FRONT** 



### **FRONT CARD**



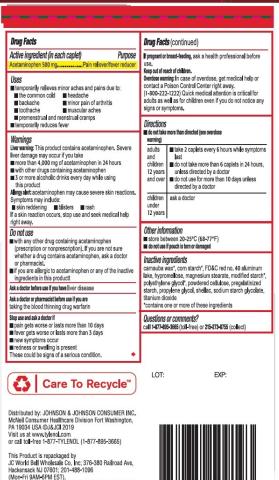
## **BACK**







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



#### TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

from a product manufactured by JOHNSON & JOHNSON

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50269-008(NDC:50580-449) Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

Inactive Ingredients			
Ingredient Name	Strength		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POWDERED CELLULOSE (UNII: SMD1X3XO9M)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SHELLAC (UNII: 46N107B710)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
STARCH, CORN (UNII: O8232NY3SJ)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	TYLENOL;500
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-008- 06	6 in 1 BOX	11/15/2019	
1		2 in 1 BLISTER PACK		
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	11/15/2019	

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

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-008)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
McNeil Healthcare LLC		831188763	manufacture(50269-008)	

Revised: 11/2023 JC World Bell Wholesale Co., Inc.