

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

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 style="list-style-type: none"> • take 2 caplets every 6 hours while symptoms last • do not take more than 6 caplets in 24 hours, unless directed by a doctor • 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 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** 215-273-8755

Package Labeling:





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

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Uses

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 - backache
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- 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.

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.

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. (1-800-222-1222) 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)

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Other information

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LOT: EXP:

Distributed by: JOHNSON & JOHNSON CONSUMER INC., McNeil Consumer Healthcare Division Fort Washington, PA 19034 USA ©J&J 2019
 Visit us at www.tylenol.com or call toll-free 1-877-TYLENOL (1-877-895-3665)



This Product is repackaged by JC World Bell Wholesale Co, Inc; 376-380 Railroad Ave, Hackensack NJ 07601; 201-488-1096 (Mon-Fri 9AM-6PM EST), from a product manufactured by JOHNSON & JOHNSON

TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

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
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
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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: 70097M6130)	

Product Characteristics

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

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	Business Operations
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-008)

Establishment

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

Revised: 11/2023

JC World Bell Wholesale Co., Inc.