TYLENOL EXTRA STRENGTH- acetaminophen tablet, film coated
Kenvue Brands LLC

TYLENOL Extra Strength

Drug Facts

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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

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
■ 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.

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)**

adults and children 12 years and over	■ 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 blister unit is torn or broken**

Inactive ingredients

carnauba wax, 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.

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-491-10

To re-order reference the NDC Code

TYLENOL ®
FOR ADULTS

Acetaminophen Pain Reliever - Fever Reducer

Extra Strength

FOR HOSPITAL USE ONLY. NOT FOR HOUSEHOLD USE. PACKAGE IS NOT CHILD-RESISTANT.

100 Caplets
500 mg each

10 Blister Cards with 10 Individual Blisters

TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-491
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics			
Color	white (white with red print)	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	TYLENOL;500
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50580-491-70	1 in 1 CARTON	08/30/2025	
1		700 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-491-01	1 in 1 CARTON	08/30/2025	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50580-491-10	10 in 1 CARTON	08/30/2025	

3		10 in 1 BLISTER PACK; 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	08/30/2025	

Labeler - Kenvue Brands LLC (118772437)

Revised: 1/2026

Kenvue Brands LLC