TYLENOL EXTRA STRENGTH- acetaminophen tablet, coated
Kenvue Brands LLC

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

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

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 carton is opened or neck wrap or foil inner seal imprinted with "SAFETY SEAL®" is broken or missing**

Inactive ingredients

carnauba wax [1], castor oil [1], corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, polyethylene glycol [1], powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

1 contains one or more of these ingredients

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-451-50

See New Warnings Information & Directions

TYLENOL ®

Pain Reliever
Fever Reducer
Acetaminophen

EXTRA
STRENGTH
For Adults

50 CAPLETS
500 mg each

Caplets

For Hospital and Government Use Only

TYLENOL EXTRA STRENGTH

acetaminophen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50580-451
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CASTOR OIL (UNII: D5340Y2I9G)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	TYLENOL;500;HOSPITAL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-451-03	150 in 1 CARTON	08/19/1994	11/30/2016
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:50580-451-10	10 in 1 CARTON	06/30/2014	01/31/2019
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-451-50	1 in 1 CARTON	08/19/1994	
3		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:50580-451-70	700 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/1994	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/19/1994	

Labeler - Kenvue Brands LLC (118772437)

Revised: 2/2025 Kenvue Brands LLC