TYLENOL EXTRA STRENGTH- acetaminophen tablet, film 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

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 carton is opened. Do not use if foil inner seal imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

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

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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 50580-449-96

TYLENOL ®
FOR ADULTS

Acetaminophen
Pain Reliever
Fever Reducer

Extra Strength
Actual Size

50 Caplets
500 mg each

TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information

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

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:50580-449-00	1 in 1 CARTON	08/19/1984	
1		125 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50580-449-05	1 in 1 CARTON	08/19/1984	
2		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:50580-449-08	2 in 1 POUCH; Type 0: Not a Combination Product	08/19/1984	
4	NDC:50580-449-09	1 in 1 CARTON	08/19/1984	
4		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:50580-449-10	50 in 1 TRAY	08/19/1984	

5		2 in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:50580-449-11	50 in 1 TRAY	08/19/1984	
6		2 in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:50580-449-13	3 in 1 CARTON	08/19/1984	
7		2 in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:50580-449-14	2 in 1 POUCH; Type 0: Not a Combination Product	08/19/1984	
9	NDC:50580-449-15	10 in 1 VIAL, PLASTIC; Type 0: Not a Combination Product	08/19/1984	
10	NDC:50580-449-23	1 in 1 CARTON	08/19/1984	
10		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:50580-449-31	1 in 1 CARTON	08/19/1984	
11		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:50580-449-34	325 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/1984	
13	NDC:50580-449-35	1 in 1 CARTON	08/19/1984	
13		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
14	NDC:50580-449-36	1 in 1 CARTON	08/19/1984	
14		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
15	NDC:50580-449-61	1 in 1 CARTON	08/19/1984	
15		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
16	NDC:50580-449-62	325 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/1984	
17	NDC:50580-449-84	2 in 1 POUCH; Type 0: Not a Combination Product	08/19/1984	
18	NDC:50580-449-85	50 in 1 TRAY	08/19/1984	
18		2 in 1 POUCH; Type 0: Not a Combination Product		
19	NDC:50580-449-86	50 in 1 TRAY	08/19/1984	
19		2 in 1 POUCH; Type 0: Not a Combination Product		
20	NDC:50580-449-87	3 in 1 CARTON	08/19/1984	
20		2 in 1 POUCH; Type 0: Not a Combination Product		
21	NDC:50580-449-12	12 in 1 PACKAGE	10/21/2014	
21		10 in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
22	NDC:50580-449-96	1 in 1 CARTON	06/25/2018	
22		50 in 1 BOTTLE; Type 0: Not a Combination Product		
23	NDC:50580-449-97	249 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/28/2019	
24	NDC:50580-449-98	110 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/28/2019	
25	NDC:50580-449-66	2 in 1 CARTON	05/01/2024	

25		100 in 1 BOTTLE; 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	08/19/1984	

Labeler - Kenvue Brands LLC (118772437)

Revised: 2/2025 Kenvue Brands LLC