

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	<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 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

015001899403



Drug Facts

Active ingredient (in each caplet) *Pain reliever & fever reducer*
Acetaminophen 500 mg

Uses

- temporarily relieve minor aches and pains due to:
 - headaches
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - menstrual and menstrual cramps
 - temporarily reduce 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 alcohol drinks every day while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). You are not sure whether eating contains acetaminophen, ask a doctor or pharmacist.
- if you are taking: benzamides, or any other health 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 blood thinning drugs, 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
- weakness or swelling is present

This occurs the signs of an allergic condition.

If pregnant or breast-feeding, ask a health professional before use.

NDC 50580-451-50

See New Warnings Information & Directions

TYLENOL®

Pain Reliever
Fever Reducer

EXTRA STRENGTH

Acetaminophen

50 CAPLETS
500 mg each

For Adults
Caplets

For Hospital and Government Use Only

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NDC 50580-451-50

See New Warnings Information & Directions

TYLENOL®

Pain Reliever
Fever Reducer

EXTRA STRENGTH

Acetaminophen

50 CAPLETS
500 mg each

For Adults
Caplets

For Hospital and Government Use Only

TYLENOL®

Pain Reliever
Fever Reducer

EXTRA STRENGTH

For Adults
50 Caplets

For Hospital and Government Use Only

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 Fort Washington, PA 19034 USA
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 Visit us at www.tylenol.com
 or call 1-877-TYLENOL (1-877-895-3665)

Contains No Aspirin

EXP: 3 50580-451-50 2

Drug Facts (continued)

Keep out of reach of children. One or two warnings: In case of overdose, get help or contact Poison Control Center right away: (1-800-272-1232). 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)
- take 2 caplets every 6 hours with symptoms but do not take more than 6 caplets in 24 hours
- infants of 2 years of age by a doctor
- 12 years and older: do not use for more than 10 days unless directed by a doctor
- children under 12 years

Other information

- store between 20°-25° C (68°-77° F)
- do not use if certain is opened or neck wavy or full inner seal is impaired with "SAFETY SEAL" is broken or missing

Inactive ingredients: carboxymethylcellulose, croscarmellose, docusone, polyethylene glycol, powdered cellulose, pregelatinized starch, polyethylene glycol, sodium starch glycolate, titanium dioxide

*contains one or more of these ingredients

Questions or comments?
 call 1-877-895-3665 (toll-free) or 215-273-5055 (local)

015001899403

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: 46N107B710)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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