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

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#### TYLENOL® Extra Strength

#### **Drug Facts**

#### **Active ingredient (in each caplet)**

Acetaminophen 500 mg

#### **Purpose**

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Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
- the common col
- headache
- backache
- minor pain of arthritis
- toothach
- 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.

- 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 andchildren 12 years and over	<ul><li>■ take 2 caplets every 6 hours while symptoms last</li><li>■ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li><li>■ do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	ask a doctor

#### Other information

- store between 20-25°C (68-77°F)
- $\blacksquare$  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, crospovidone, FD&C red no. 40, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

#### Questions or comments?

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

#### PRINICIPAL DISPALY PANEL

NDC 50580-108-25

TYLENOL ®

**FOR ADULTS** 

**Acetaminophen** 

**Pain Reliever** 

**Fever Reducer** 

**Extra Strength** 

**Actual Size** 

225 Caplets

500 mg each



#### TYLENOL EXTRA STRENGTH

acetaminophen tablet, film coated

Prod	luct	Infor	mation
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-108
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Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
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ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 500 mg

## **Inactive Ingredients**

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Ingredient Name	Strength
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

#### **Product Characteristics**

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

# **Packaging**

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50580-108- 25	1 in 1 CARTON	10/13/2025			
1		225 in 1 BOTTLE; Type 0: Not a Combination Product				

Market	ing	Infor	mati	on

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Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

# Labeler - Kenvue Brands LLC (118772437)

Revised: 9/2025 Kenvue Brands LLC