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

TYLENOL®

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- -headache
- -muscular aches
- -backache
- -minor pain of arthritis
- -the common cold
- -toothache
- -premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg) in 24 hours for adults or 5 caplets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 the user

■ has liver disease ■ is a child with pain of arthritis

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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	 ■ take 2 caplets every 4 to 6 hours while symptoms last ■ do not take more than 10 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
children 6 years to under 12 years	 take 1 caplet every 4 to 6 hours while symptoms last do not take more than 5 caplets in 24 hours do not use for more than 5 days unless directed by a doctor
children	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, hypromellose, magnesium stearate, powdered cellulose, pregelatinized starch, sodium starch glycolate

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

PRINCIPAL DISPLAY PANEL

325 mg

NDC 50580-475-11

To re-order reference the NDC Code

TYLENOL®

Acetaminophen Pain Reliever - Fever Reducer

Regular Strength

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

100 Caplets

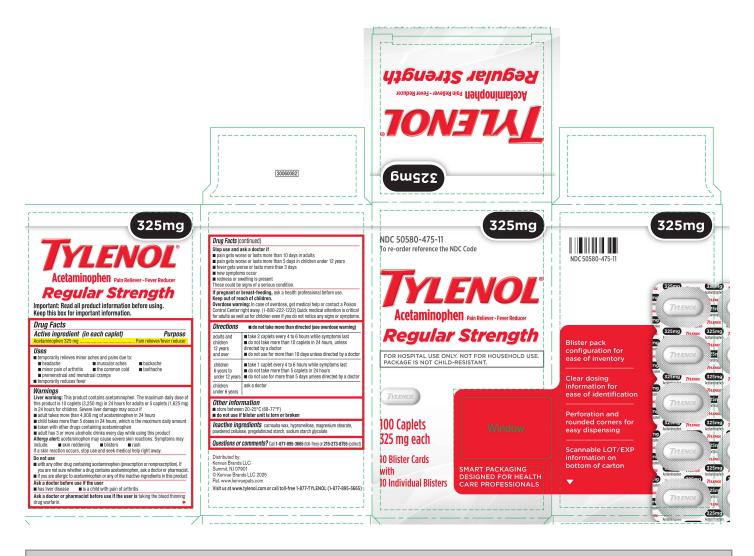
325 mg each

10 Blister Cards

with

10 Individual Blisters

SMART PACKAGING
DESIGNED FOR HEALTH
CARE PROFESSIONALS



TYLENOL REGULAR STRENGTH

acetaminophen tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-475

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 325 mg

Inactive Ingredients

Ingredient Name	Strength
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

MAGNESIUM STEARATE (UNII: 70097M6I30)

Product Characteristics							
Color	white	Score	no score				
Shape	OVAL	Size	16mm				
Flavor		Imprint Code	TYLENOL;325				
Contains							

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:50580- 475-11	10 in 1 CARTON	08/30/2025			
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:50580- 475-50	1 in 1 CARTON	08/30/2025			
2		50 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:50580- 475-10	1 in 1 CARTON	08/30/2025			
3		1000 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	08/30/2025			

Labeler - Kenvue Brands LLC (118772437)

Revised: 8/2025 Kenvue Brands LLC