

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

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**TYLENOL Regular Strength**

***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**

**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 12 years and over	<ul style="list-style-type: none"><li>▪ take 2 caplets every 4 to 6 hours while symptoms last</li><li>▪ do not take more than 10 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 6 years to under 12 years	<ul style="list-style-type: none"><li>▪ take 1 caplet every 4 to 6 hours while symptoms last</li><li>▪ do not take more than 5 caplets in 24 hours</li><li>▪ do not use for more than 5 days unless directed by a doctor</li></ul>

children  
under 6  
years

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, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

### Questions or comments?

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

### PRINCIPAL DISPLAY PANEL

325mg

NDC 50580-458-11

To re-order reference the NDC Code

TYLENOL<sup>®</sup>

Acetaminophen Pain Reliever - Fever Reducer

Regular Strength

100 Caplets

325 mg each

10 Blister Cards

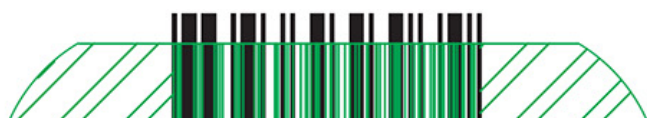
with

10 Individual Blisters

SMART PACKAGING  
DESIGNED FOR HEALTH  
CARE PROFESSIONALS

FOR HOSPITAL USE ONLY. NOT FOR HOUSEHOLD USE.

PACKAGE IS NOT CHILD-RESISTANT.



**Regular Strength**

Acetaminophen Pain Reliever - Fever Reducer

**TYLENOL**

**325mg**

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**325mg**



NDC 50580-458-11

**325mg**

Blister pack  
configuration for  
ease of inventory

Clear dosing  
information for  
ease of identification

Perforation and  
rounded corners for  
easy dispensing

Scannable LOT/EXP  
information on  
bottom of carton





325mg

# TYLENOL®

Acetaminophen Pain Reliever - Fever Reducer

## Regular Strength

Important: Read all product information before using.  
Keep this box for important information.

### Drug Facts

Active ingredient (in each caplet)	Purpose
Acetaminophen 325 mg	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
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- 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**

### Drug Facts (continued)

#### Stop use and ask a doctor if

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adults and children 12 years and over

- 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 under 6 years

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, corn starch, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide

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

Active ingredient made in India

Distributed by:

**JOHNSON & JOHNSON CONSUMER INC.**

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA

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Visit us at [www.tylenol.com](http://www.tylenol.com) or call toll-free 1-877-TYLENOL (1-877-895-3665)

# TYLENOL REGULAR STRENGTH

acetaminophen tablet, film coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-458
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 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)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

## Product Characteristics

Color	white (White with red print)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	Tylenol;325
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-458-11	10 in 1 CARTON	07/17/2020	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-458-50	1 in 1 CARTON	07/17/2020	
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

3	NDC:50580-458-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/17/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		07/17/2020	

**Labeler** - Kenvue Brands LLC (118772437)