

**TYLENOL REGULAR STRENGTH- acetaminophen tablet, film coated**  
**Johnson & Johnson Consumer Inc.**

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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

**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	ask a doctor

years |

### **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®

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 AND GOVERNMENT USE ONLY

125617



**Regular Strength**

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NDC 50580-458-11

**325mg**

Blister pack configuration for ease of inventory

Clear dosing information for ease of identification

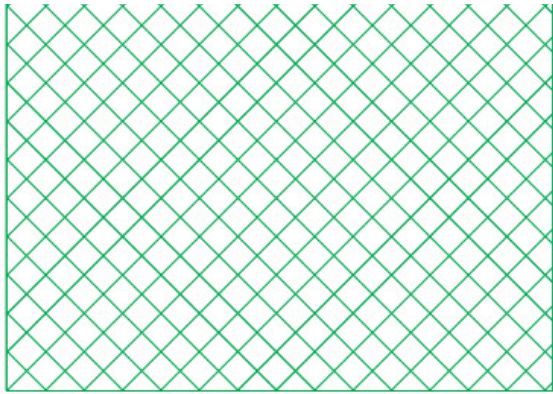
Perforation and rounded corners for easy dispensing

Scannable LOT/EXP information on bottom of carton

Window

SMART PACKAGING  
DESIGNED FOR HEALTH  
CARE PROFESSIONALS





30049015/125617

**325mg**

# **TYLENOL<sup>®</sup>**

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**Regular Strength**

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### Drug Facts (continued)

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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)

125617



# TYLENOL REGULAR STRENGTH

acetaminophen tablet, film coated

## Product Information

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

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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-	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a	07/17/2020	

458-10	Combination Product	07/17/2020	
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/17/2020	

**Labeler** - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024

Johnson & Johnson Consumer Inc.