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

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	▪ 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). Avoid high humidity. Protect from light.
- **do not use if any individual blister unit is open or torn**

Inactive ingredients

carnauba wax, crospovidone, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, medium chain triglycerides, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, shellac glaze, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

325mg

NDC 50580-600-02
To re-order reference the NDC code

TYLENOL®
Acetaminophen Pain Reliever - Fever Reducer
Regular Strength

EZ DOSE™

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

313493

TYLENOL®

Acetaminophen Pain Reliever - Fever Reducer

Regular Strength

325mg

325mg

NDC 50580-600-02

To re-order reference the NDC code

TYLENOL®

Acetaminophen Pain Reliever - Fever Reducer

Regular Strength

TYLENOL 325 HOSPITAL

100 Caplets
325 mg each

10 Blister Cards
with
10 Individual Blisters

FOR HOSPITAL AND GOVERNMENT USE ONLY

EZ DOSE™

SMART PACKAGING DESIGNED FOR HEALTH CARE PROFESSIONALS

EZ DOSE™

Blister pack configuration for ease of inventory

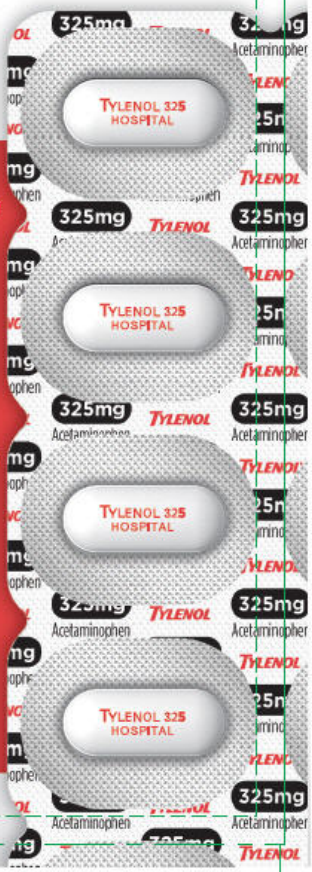
Clear dosing information for ease of identification

Perforation and rounded corners for easy dispensing

Scannable LOT/EXP information on bottom of carton

325mg

NDC 50580-600-02



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313493

325mg

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Acetaminophen Pain Reliever - Fever Reducer

Regular Strength

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Drug Facts (continued)

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Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA

Care To Recycle™

Visit us at 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:50580-600
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)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	TYLENOL;325;HOSPITAL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-600-01	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2017	

2	NDC:50580-600-02	10 in 1 CARTON	05/31/2017	10/22/2021
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-600-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/31/2017	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 1/2024 Johnson & Johnson Consumer Inc.